A STUDY ON
CEGANA VATHAM
(Cervical Spondylosis)

Dissertation Submitted To

THE TAMIL NADU Dr. M.G.R. Medical University

Chennai – 32

For the Partial fulfillment for the Award of Degree of

DOCTOR OF MEDICINE (SIDDHA)

(Branch – III, SIRAPPU MARUTHUVAM)

DEPARTMENT OF SIRAPPU MARUTHUVAM

Government Siddha Medical College

Palayamkottai – 627 002.

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PALAYAMKOTTAI, TIRUNELVELI-627002,
TAMILNADU, INDIA.

Phone: 0462-2572736 / 2572737/ Fax:0462-2582010
Email: gsmc.palayamkottai@gmail.com

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This is to certify that the dissertation entitled **"A STUDY ON CEGANA VATHAM"** is a bonafide work done by **Dr. D. SUBATHRA, GOVERNMENT SIDDHA MEDICAL COLLEGE, PALAYAMKOTTAI** in partial fulfillment of the University rules and regulations for award of **M.D (SIDDHA), BRANCH - III SIRAPPU MARUTHUVAM** under my guidance and supervision during the academic year **2015-2018 OCTOBER.**

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PALAYAMKOTTAI, TIRUNELVELI-627002,
TAMILNADU, INDIA.

Phone: 0462-2572736 / 2572737/ Fax:0462-2582010
Email: gsmc.palayamkottai@gmail.com

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I hereby declare that this dissertation entitled **"A STUDY ON CEGANA VATHAM"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. M. AHAMED MOHIDEEN., M.D(s).,** Associate Professor, PG - Department of Sirappu Maruthuvam, Govt. Siddha Medical College, Palayamkottai and the dissertation has formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

Date :

Place: Signature of Candidate

Dr. D. Subathra

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A. Rajasekaran

Dr. A. Rajasekaran
Biological Scientist and IAEC Chairperson

PRINCIPAL
KMCH College of Pharmacy,
Kovai Estate, Kalapatti Road
Coimbatore - 641 048.
Tamil Nadu, INDIA

KMCH College of Pharmacy * Coimbatore - 641 035

15/2/18

Dr. D. Kannan
Main Nominee [CPCSEA]

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TIRUNELVELI – 627 002
TAMIL NADU INDIA

Ph : 0462-2572736 / 2572737 / 2582010 Fax : 0462-2582010
Email ID : gsmc.palayamkottai@gmail.com

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Address of Ethical committee	Government Siddha Medical College Palayamkottai – 627002 Tirunelveli District
Principal investigator	Dr.D.Subathra. I Year, PG Dept of Sirappu Maruthuvam Reg.No :
Guide	Dr.M.Ahamed mohideen.M.D(s) Reader Dept of sirappu maruthuvam
Dissertation topic	An open clinical Study to evaluate the clinical efficacy of siddha sasthric formulation "**MILAGULEGIYAM**"(Internal)"SEERAGA THYLAM "for the treatment of **CEGANA VATHAM**
Document field	1. Protocol2. Date Collection Form 3. Patient Information Sheet 4. Consent form5. SAE (Pharmacovigilance)
Clinical / Non Clinical trial Protocol	Clinical trial protocol – Yes
Informed consent document	Yes
Any other document	Case sheet, Investigation document
Date of IEC approval & it's Number	GSMC/3.IEC/2016/III-28/20.07.16

We approve the trial to be conducted in its presented form.

The Institutional Ethical committee expects to be informed about the process report to be submitted to the IEC at least annually of the study, any SAE occurring in the course of the study and changes in the protocol and submission of final report.

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Email id :gsmc.palayamkottai@gmail.com

CERTIFICATE OF GUNAPADAM AUTHENTICITY

Certified the following plant drugs used in siddha formulation **SEERAGA THYLAM (EXTERNAL)** for management of **CEGANA VATHAM(Cervical spondylosis)** taken up for post-graduation dissertation studies by **Dr.D.SUBATHRA M.D (S),. (REG.NO:321513009)** PG scholar, department of sirappu maruthuvam are correctly identified and authenticated through Visual inspection / Organoleptic characters / Experience, Education & Training morphology, microscopical and taxonomical methods.

METALS & MINERAL INGREDIENTS OF VISHNU CHAKRA MATHIRAI

S.NO	TAMIL NAME	ENGLISH NAME	CHEMICAL NAME
1.	Indhuppu	Rock salt	Sodium chloride impura

Station: Palayamkottai

Date: 14.06.17.

Authorized signature 14/6/17

Dr. A. KINGSLY MD (S)
Reader
Head of the Department
PG Gunapadam
Govt. Siddha Medical College
Palayamkottai.

9.	kadugurohini	Picrorhiza kurroa	Scrophulariaceae	Rhizome
10.	Kirambu	Syzygium aromaticum	Myrtaceae	Flower bud
11.	Kadukkai pinchu	Terminalia chebula	combretaceae	pinchu

Station: Palayamkottai

Date:

Authorized signature

Dr. S. SUTHA, M.Sc.,M.Ed.,Ph.D.,
Associate Professor
Dept. of Medicinal Botany
Govt. Siddha Medical College
Palayamkottai, Tirunelveli - 2.

GOVERNMENT SIDDHA MEDICAL COLLEGE

PALAYAMKOTTAI-627002

TAMILNADU,INDIA

Ph: 0462-2572736/2572737/fax:0462-2582010

Email id :gsmc.palayamkottai@gmail.com

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INGREDIENTS MILAGU LEGIYAM

S.NO	DRUGS	BOTANICAL NAME	FAMILY	PART USED
1.	Milagu	Piper nigrum	Piperaceae	Unriped fruit
2.	Akirakaram	Anacyclus pyrethrum	Asteraceae	Root
3.	Seeragam	cuminum cyminum	Apiaceae	Fruit
4.	Kirambu	Syzygium aromaticum	Myrtaceae	Flower Bud
5.	Vaividangam	Emblica ribes	Primulaceae	Seed
6.	Aelam	Eletaria cardomum	Zingiberaceae	Fruit
7.	Kostam	Saussurea lappa	Asreraceae	Root
8.	Athimathuram	Glycyrriza glabra	Fabaceae	Root
9.	Pathiri	Myrstica fragrans	Myristicaceae	Aril
10.	Narukku moolam	Piper longum	Piperaceae	Root

INGREDIENTS OF SEERAGA THYLAM

S.NO	DRUGS	BOTANICAL NAME	FAMILY	PART USED
1.	Seeragam	Cuminum cyminum	Apiaceae	Seed
2.	Kostam	Saussurea lappa	Asteraceae	Root
3.	Karkadaga shingi	Rhus succedanea	Anacardiaceae	Gall
4.	kichchilikilangu	Curcuma zedoria	Zingiberaceae	Rhizome
5.	Omam	Trachyspermum ammi	Apiaceae	Fruit
6.	Arathai	Alpinia galanga	Zingiberaceae	Root
7.	Valuluvai	Celastrus paniculatus	celastraceae	Seed
8.	Karpogarisi	Psoralea corylifolia	Fabaceae	Seed

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"MILAGU LEGIYAM (Internal), SEERAGATHYLAM (External)" for the treatment of ……"LEGANA VATHAM."…… had been approved by the screening committee.

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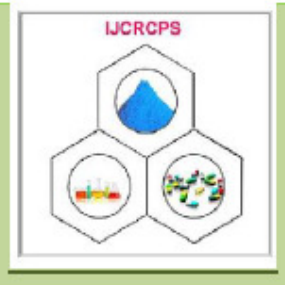

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[1,2] PG student, Department of PG Sirappu Maruthuvam, Government Siddha Medical College, Palayamkottai, Tamil nadu, India

[3]Professor & HOD, Department of PG Sirappu Maruthuvam, Government Siddha Medical College, Palayamkottai, Tamil nadu, India

[4]Grade II Lecturer, Department of PG Sirappu Maruthuvam , Government Siddha Medical College , Palayamkottai Tamil nadu India

[5]Grade II Lecturer, Department of PG Sirappu Maruthuvam , Government Siddha Medical College, Palayamkottai, Tamil nadu, India

Corresponding authors: Dr. Kirubakaran R, Dr.Subathra D,

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[1, 2] PG Scholars, Department of PG Sirappu Maruthuvam
Government Siddha Medical College, Palayamkottai, Tamil nadu, India

[3]Professor & HOD, Department of PG Sirappu Maruthuvam
Government Siddha Medical College, Palayamkottai Tamil nadu, India

[4]Associate Professor, Department of PG Sirappu Maruthuvam
Government Siddha Medical College , Palayamkottai Tamil nadu, India

[5]Grade II lecturer, Department of PG Sirappu Maruthuvam,
Government Siddha Medical College, Palayamkottai

Corresponding authors: Dr.Subathra D, Dr. Kirubakaran R,

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Editor in Chief
IJCRBM
Website: www.darshanpublishers.com
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INTRODUCTION

Siddha system of medicine is primitive medicine. Hence it is unique when compared to any other Indian medical system. It has a rich treasure of medicinal knowledge that includes the use of herbs, metals, and minerals. siddha system is based on a combination of ancient medicinal practises and spiritual disciplenes. This specialized medical practice was created by the siddhars.They discovers many natural remedies which are used for the wide range of diseases.

Siddha system emphasizes not only a healthy body but a peaceful mind and pure soul.

According to thiruvalluvar

"மிகினும் குறையினும் நோய் செய்யும் நூலோர்
வளிமுதலா எண்ணிய மூன்று".

If the three doshas are normal in function, health is maintained. Any change in the proportions of vatham, pitham and kabam may leads to disease.

In yugi Vaithiya Chinthamani - 800 Siddhar Yugi Munivar has classified Vatha disease into 80 types . Cegana Vatham is one among them and the symptoms are pain in the neck, giddiness, pain in the limbs, burning sensation of the eyes, pain all over the body like a sting of a scorpion.

Most of the symptoms present in Cegana Vatham can be correlated to those of Cervical spondylosis. Nowadays pain in the neck has become a matter of major concern. It is mainly due to life style modification. Pain in the neck is experienced by many people, especially software professionals who spend most of their time in front of the computers. Apart from them Manual workers who have to lift heavy weight also undergo the same problem. So the chances of developing Cervical Spondylosis are also highly increased. The common age group affected by cervical spondylosis is geriatric age group. Repeated trauma to cervical spine related to specific occupation like carrying axial loads, typing computer operation, desk work jobs etc. Play an important role in producing even at lesser age group.

Cervical spondylosis refers to normal age related degenerative changes that occur in the cervical spine. These changes become much more prevalent as individual age. Radiographic evidence of cervical disk disease is present in 25% of asymptomatic patients under age 40, and 85% of asymptomatic patients over 60 yrs of age cervical disk disease can remain asymptomatic in many cases. But symptoms can

include axial neck pain, cervical radiculopathy and cervical spondylotic myelopathy. At some point during life, nearly everyone will be affected by neck pain.

As elsewhere cervical spondylosis is extremely common in India. The management scenario of cervical spondylosis is confusing and many times irrational. Our belief in traditional system of medicine is extremely high. In siddha literature, several formulations have been indicated for the treatment of vadha disease. In AATHMARATCHAMIRTHAM a drug "**MILAGU LEGIYAM"** has been indicated for Vatha disease. Hence I have selected this polyherbal formulation MILAGU LEGIYUM-6grm twice a day to evaluate the synergic therapeutic efficacy in the treatment of "CEGANA VATHAM" (CERVICAL SPONDYLOSIS) and also I have selected the **"SEERAGA THYLAM"** (External)-30 ml from SARBENTHARA VAITHIYA MURAIGAL – VATHAROGA CHIKKICHAI. These medicines contain various ingredients which modify the vitiated vatham.

"Sirappu Maruthuvam" is one among the distinguished branches of siddha system where it consists of varmam, thokkanam, ottradam, yogam and kaya kalpam. Mainly the vatha diseases are treated through Internal medicine, external medicine and varmam.

varmam is one of the best external therapies in siddha system in alleviating pain in Cegana Vatham is also evaluated as a complementary therapy with trial medicines.

The purpose of this work is to provide an overview of evaluation and treatment of the patient with a special disorder cervical spondylosis.

The trial drugs were prepared by the author and were tried in 40 cases of Cegana vatham of varied aetiology and the clinical study was undertaken in the IP and the outpatient post graduate department of sirappu maruthuvam and the follow up study of all the cases was done in the post graduate out patient.

AIM AND OBJECTIVE

AIM:

To evaluate the clinical efficacy of "**MILAGU LEGIYAM" (**internal) and "**SEERAGATHYLAM**"(external) for the treatment of **CEGANA VATHAM** (CERVICAL SPONDYLOSIS).

PRIMARY OBJECTIVE :

To evaluate the clinical efficacy of "**MILAGU LEGIYAM" (**internal) and "**SEERAGATHYLAM**"(external) for the treatment of **CEGANA VATHAM** (CERVICAL SPONDYLOSIS).

SECONDARY OBJECTIVE:

- To study the Siddha basic principles like envagai thervukkal including neerkkuri and neikkuri.
- To evaluate the safety profile of the trial medicine.
- To Evaluate the pharmacological study of trial medicine

REVIEW OF LITERATURE

SIDDHA ASPECT

செகனவாதம்

சித்த மருத்துவத்தில் வாத, பித்த, கப முக்குற்றங்களை அடிப்படையாகக் கொண்டு நோய்களானது 4448 வகைகளாகப் பிரிக்கப்பட்டுள்ளன. "யூகி வைத்திய சிந்தாமணி" நூலில் கூறப்பட்டுள்ள 80 வகை வாதங்களில் செகனவாதமும் ஒன்று.

cegana vatham details are distribute under the following headings.

Definition

A kind of neurological pain (vadha disease) affecting the cervical vertebral region and extending to the upper limbs and is associated with heaviness of body, giddiness, burning sensation of the eyes, discharge of urine with pain (strangury of dysuria).

-T.V. Sambasivam pillai dictionary P.No.1752

Aetiology

The siddha literatures portrays the reason for diseases are any alteration in vatha,,pitham,kabam (Mukutrangal)

The most common causes for cegana vatham are same that of the etiological factors, which aggrevate vatha disease. The aetiological factors are explained by various authors in text books they are follows,

1.அகத்தியர் கன்மகாண்டம்-300

வாத கன்ம வரலாறு

"நூலென்ற வாதம் வந்த வகைதானேது
நுண்மையாயக் கன்மத்தின் வகையைக் கேளு
காலிலே தோன்றியது கடுப்பதேது
கைகாலில் முடக்கியது வீக்கமேது
கோலிலே படுகின்ற விருட்சமான
குழந்தை மரந்தன்னை வெட்டல் மேல்தோல் சீவல்
நாவிலே சீவசெந்து கால்முறித்தல்
நல்ல கொம்பு தாழை முறித்தல் நலித்தல் காணே"

- **அகத்தியர் கன்ம காண்டம் -300 பாடல் 56**

2. யூகி வைத்திய சிந்தாமணி -800-ல்

"என்னவே வாதந்தா னெண்பதாகும்
இகத்திலே மனிதர்களுக் கெய்யுமாறு

பின்னவே பொன்தனையே சோரஞ்செய்து
பெரியோர்கள் பிராமணரைத் தூடணித்தும்
வன்தேவச் சொத்தில் சோரஞ்செய்து
மாதா பிதா குருவை மறந்த பேர்க்கும்
கன்னவே வேதத்தை நிந்தை செய்தால்
காயத்திற் கலந்திடுமே வாதந் தானே"

- **யூகி வைத்திய சிந்தாமணி பாடல் - 243**

"தானென்ற கசப்போடு துவர்ப்புறைப்பு
சாதகமாய் மிஞ்சிகிலும் சமைத்த வண்ணம்
ஆனென்ற வாறினது புசித்தாலும்
ஆகாயத் தேறலது குடித்த லாலும்
பானென்ற பகலுறக்க மிரா விழிப்பு
பட்டினியெ மிகவுறுதல் பாரமெய்தல்
தேனென்ற மொழியார் மேற் சிந்தையாதல்
சீக்கிரமாய் வாதமது செனிக்குந் தானே"

- **யூகி வைத்திய சிந்தாமணி – பாடல் 244**

"வாதவர்த்தி தனைகால மேதோ வென்னில்
மருவுகின்ற வானிகர்க் கடகமாகும்
ஆதவைப் பசியோடு கார்த்திகை தன்னில்
அடருமே மற்றமா தங்கள் தன்னில்
போதவே சமிக்குகின்ற காலமாகும்".

- **யூகி வைத்திய சிந்தாமணி – பாடல் 245**

"ஆனான வரன்றனையே மதியா மாந்தர்
அகதி பரதேசியர்கட் கன்ன மீயார்
கோனான குருமொழியை மறந்த பேர்கள்
கொலை களவு பொய் காமங் குறித்த பேர்க்கு
ஊனான சடந்தன்னில் வாதம் வந்து
உற்பவிக்கும் வேதத்தின் உண்மைதானே"

- **யூகி வைத்திய சிந்தாமணி – பாடல் 253**

"பகரவே வாதமது கோபித்தப்போ
பண்பாகப் பெண்போகமது தான் செய்யில்
நகரவே வெகுதூர வழி நடக்கில்
நளிரான காற்றுமே பனிமேற்பட்டால்
மிகரவே காய்கள் கனி கிழங்கு தன்மை
மிக வருந்தி மீறியே தயிர்தான் கொண்டால்

முகரவே முதுகெலும்பை முறுக்கி நொந்து

முழங்காலும் கணைக்காலும் கடுப்பு உண்டாகுமே”

- **யூகி வைத்திய சிந்தாமணி – பாடல் 245**

3. அகத்தியர் குணவாகடம்

“விவரமடா அசதி சன்னி மூளை நோவு

விரிவான மூளையது மிருதுவாகி

அவனிதனில் திடமாகப் போவதாலும்

அப்பனே மூத்திரக் குண்டிக்காயயண் வியாதியாலும்

தவ முனிவர் தீர்காக்கை மேக ரோகம்

தன்மையுள்ள முத்தண்டுக் கொடி வியாதி

அவமிலாப் பரிச நரம்பழுத்தங் கண்டால்

அணுகுமடா வாதநோய் ஆகும்பாரே”

To sum up

The causative factors for the manifestation of vatha diseases are the following intrinsic and extrinsic factors.

Intrinsic factors

1. Diet

Intake of food items which are excessive in bitter, astringent and pungent taste, intake of previous day cooked food item, drinking rain water, harmful combination like taking excessive curd after eating fruits, vegetables and tubers causes toxic factors which affects bones and muscle.

2. Psycho social aspects

Breach of trust, cutting the living branches and removing leaves, cutting the trees, splitting the chastity of a women, abusing the holy men and vitualists, abusing the holy scripts, utilize the properties of charities, ungratefulness towards mother, father and teacher, ignore the divinity, refusing the food for destitute and saints, forgetting the advice of preceptors and wickedness such as murdering, stealing, involving in immoral activities, sexual perversion, removing the bark of living tree, breaking the leg of the animals.

Even though on the above lines our legends siddhars explain the common causes. We cannot understand how it produces the distress of cegana vatham. The author denotes that all this view should be for further analysis.

Extrinsic factors

- Exposure to dampness and cold.
- Precipitation of the disease in the months from Aani to Karthigai (from june to December)
- Sleeping during day time working throughout night.
- Physical strain due to excessive weight lifting.
- Walking for a long distance, exposing the body to dampness and cold.

Clinical symptoms

The clinical features of this disease cegana vatham were explained by yugimuni and pararasasekaram as follows.

1. யூகி சிந்தாமணி 800

"கேளுமே கழுத்தின் கீழரைக்கு மேலுங்
கெடியான கரமிரண்டு மிகவே நொந்து
வாளுமே சரீரமெல்லாம் கனத்திருக்கும்
வாலிபர்க்கு மனங்கண்ணு மயக்கமாகும்
ஏளுமே யிரண்டு கண்ணு மெரிச்சலுண்டா
மேற்றமாய் சலந்தானு மிறுகிக் காணுந்
தேளுமே கொட்டினது போற்கடுக்கும்
சகனவா தத்தினிடே தீர்க்கந் தானே"

- **யூகி சிந்தாமணி 800**

இந்நோய் கழுத்தின் கீழிருந்து அரையின் மேல்வரையும் உள்ள இடமும், கைகால்களும் மிக நோதல், உடல் முழுவதும் கனத்துக் காணல், மயக்கமுண்டாதல், கண்கள் எரிதல், சிறுநீர்கட்டல், உடல்முழுமையும் தேள் கொட்டியது போன்று கடுத்து நோதல் ஆகிய குறிகளை பெறும்.

2. பரராசசேகரம்

"கண்டதோர் சகன வாதங் கழுத்தின் கீழரைக்கு மேலும்
மிண்டலங் கரமிரண்டு மிகநொந்து கனத்திருக்கும்
மண்டியே திமிர்த்துக் குத்தும் வலி மிகுத்துளைவுண்டாகும்
''வண்டமர் குழலினாலோ மதியினாலுன்னுவாயே"

- Pain in the neck
- Mental depression
- Radiating pain the upper limbs and upper limbs
- Giddiness

- Constipation
- Pain perceive like sting of scorpion
- Burning sensation of the eyes
- Tingling and numbness of the upper limbs

Patho physiology

According to panchapootha theory when elemental composition is naturally altered uyir thathugal or the three humours, which are made up of these elements get deranged. This simultaneously leads to derangement of seven udal thathugal which produce the symptoms. This is the common reason for producing the cegana vatham.

Another theory which explains as follows, the etiological factors of cegana vatham are both diet that produce excessive vayu and other agents which cause vitiation of panchapootham depending upon this corresponding uyir thathu is affected. Here,

Aahayam + Air	-	Vatham
Earth + water	-	Kabam
Fire	-	Pitham

So vatham, pitham and kabam are deranged simultaneously udal thathugal get deranged. These

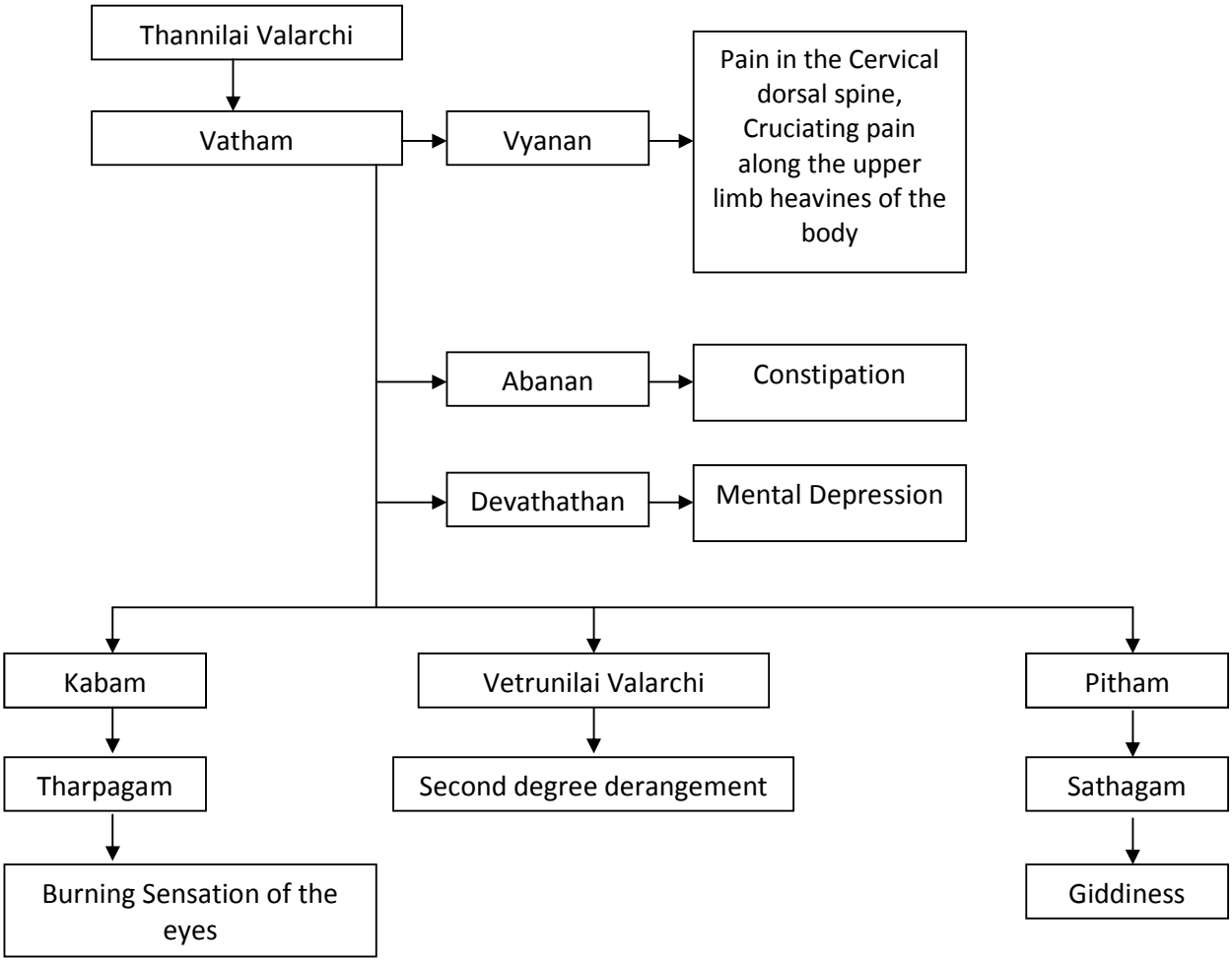
ஐம்பூதம் - தேகத்திற்கு உள்ள ஒற்றுமையாவன

பின்வரும் பாடலின் மூலம் தேகமானது பஞ்சபூதமயமானது என்பதனை அறியலாம்.

“அண்டத்தில் உள்ளதே பிண்டம்
பிண்டத்தில் உள்ளதே அண்டம்
அண்டமும் பிண்டமும் ஒன்றே
அறிந்துதான் பார்க்கும்போதே”

- சட்டமுனி

PATHOPHYSIOLOGY



“நிலம் நீர்தீவளி விசும்போடைந்தும்

கலந்தமயக் கமுலகம் இது”

- **நோய்நாடல் நோய்முதல் நாடல் பகுதி – I**

1. Earth (பிருதிவி)

Gives shape to the body and release its energy. Bones, muscles and tissues represent it in the body.

2. Water (அப்பு)

Makes the earth flexible and helps in the transmission of energy, serum, lymph, saliva etc. Represent it in the body.

3. Fire (தேயு)

Stabilizes the body and gives vigour and stimulation. Digestion and circulation represent it in the body.

4. Air (வாயு)

Catch the fire and works as a life carrier and is the support of all contact and exchange. Respiration and nervous system represent it in the body.

5. Ether (வெளி)

Ether is the creator of life itself in the body.

A harmonious, combination and function of these five elements in the body produce a healthy and beautiful life.

Man has gross physical body (ஸ்தூலம்) and subtle physical body (சூட்சுமம்).The subtle physical body is immediately behind the gross physical body and is closely connected with it.

Vatham = Air + Ether

In cegana vatham both air and ether are affected.

The life-force which is different from material energy derived. From the food, prevades the gross physical through the subtle physical.

ஐம்பூதங்கட்கும், அறுசுவைகளுக்கு முள்ள ஒற்றுமையாவன

“மண்ணுடனே புனல்தீக்கால்

முறையாகச் சேர்ந்திட்டால் வருமே இனிப்பு

திண்ணமிலம் துவர்ப்பிரசம்

சதாகதியோ டார்தீவிண் திடமாமுறைப்பும்

எண்ணரிய கசப்பு முண்டாந்

தண்ணீரில் கனவிணைப்பா லெழுமா முவர்ப்பு

உண்ணரிய அறுசுவையின்

பிறப்பிதெனும் குருசித்தருரைத்த மறையே"

- **தோற்றக்கிரம ஆராய்ச்சியும், சித்தமருத்துவ வரலாறும்**

இனிப்பு	-	பிருத்வி	+	அப்பு
புளிப்பு	-	பிருத்வி	+	தேயு
உவர்ப்பு	-	அப்பு	+	தேயு
கைப்பு	-	வாயு	+	ஆகாயம்
கார்ப்பு	-	தேயு	+	வாயு
துவர்ப்பு	-	பிருத்வி	+	அப்பு

இச்சுவைகளின் மிகுதியைக் கொண்டு, தேகத்தில் எப்பூதங்களினளவாக எக்குற்றங்கள் பிணிக்கப்பட்டிருக்கின்றன என்பதை அறியலாம்.

சகனவாதத்தில்

கைப்பு, கார்ப்பு, துவர்ப்பு ஆகிய சுவைகள் பாதிக்கப்படுவதால் அதற்கு காரணமான பூதங்களும் பாதிக்கப்படுகின்றன.

ஐம்பூதம் - முக்குற்றத்திற்கு முள்ள ஒற்றுமையாவன

வளி	=	வளி + விண்
அழல்	=	தீ
ஐயம்	=	நீர் + மண்

இரண்டிரண்டு பூதங்களின் சேர்க்கையால் உயிர்த்தாதுக்கள் உண்டாகின்றன.

பூதங்கள் பாதிக்கப்படும் உயிர்த்தாதுக்கள் போது பாதிக்கப்படுகிறது.

Vatham: Represents vayu, mind, dryness, pain flatulence, sensitiveness, lightness and also air.

Pitham: Represents gastric juice, bile, energy, heat, inflammation, anger and irritation etc.

Kabam: Represents feeling of cold, heaviness running of the nose, passing of mucous discharge and also the saliva.

Diagnosis

சித்த மருத்துவ அடிப்படையில் நோய் கணிப்பில் எண்வகைத் தேர்வு முதன்மையானது. மற்ற தேர்வுகளாவன.

1. பொறியாற்றேர்தல்
2. புலனாலறிதல்

3. வினாவுதல்
4. உயிர்தாதுக்கள்
5. உடல் தாதுக்கள்
6. ஞானேந்திரியம்
7. கன்மேந்திரியம்
8. திணைகள்
9. பருவகாலம்

1. பொறியாற்றேர்தல்

1. மூக்கு
2. நா
3. கண்
4. தோல்
5. செவி

மருத்துவர் ஐம்பொறிகளைக் கொண்டு நோயை கணிக்கமுடியும்.

சகனவாதத்தில்

கண் எரிச்சல் காணப்படும் எனவே ஐம்பொறிகளில் கண் பாதிக்கப்படுகிறது.

2. புலனாலறிதல்

1. நாற்றம் (மணம்)
2. சுவை
3. ஒளி
4. ஊறு
5. ஓசை

மருத்துவர் ஐம்புலன்களைக் கொண்டு நோயை கணிக்க முடியும்.

சகனவாதத்தில்

வலியானது கழுத்துப் பகுதி மற்றும் கைகளில் பரவுதல் காணப்படுகிறது. இரு கைகளும் மரத்துப்போதல் காணப்படுகிறது. எனவே ஐம்புலன்களில் ஊறு பாதிக்கப்பட்டுள்ளது.

3. வினாவுதல்

மருத்துவர் நோயாளியிடம் வினாவுதல் மூலம் நோயை கணிக்கமுடியும். நோயாளியால் பேச முடியாத நேரத்தில் அவன் சுற்றத்தாரிடமும் வினாவுதல் மூலம் நோயை கணிக்கமுடியும்.

எண்வகைத்தேர்வு

"நாடிப்பரிசம் நாநிறம் மொழிவிழி
மலம் மூத்திரமிவை மருத்துவ ராயுதம்"

- **நோய்நாடல் நோய் முதல்நாடல் பகுதி – I**

“மெய்க்குறி நிறந்தொனி விழி நாவிருமலம் கைக்குறி”

- தேரையர்

1. நாடி (Pulse reading),
2. ஸ்பரிசம் (Tactile sensation)
3. நா (Tongue)
4. நிறம் (Colour)
5. மொழி (Speech or voice)
6. விழி (Eye)
7. மலம் (Faeces)
8. மூத்திரம் (Urine)

1. நாடி

உடலில் உயிர் தரித்திருப்பதற்குக் காரணமான சக்தி எதுவோ அதுவே தாது அல்லது நாடி எனப்படும்.

இதுவே சீவசக்தி வாதம், பித்தம், கபம் என்ற மூன்று உயிர்த்தாது அடைந்து மூன்று குணங்களைப் பெற்று உடலையும், உயிரையும் ஒன்றுபட வளர்த்து காப்பாற்றி வருகின்றது.

சகனவாதத்தில்

1. வாதபித்தம்

“பொருளான வாதத்தில் பித்தஞ்சேர்ந்தால்

.....

கைகால் தரிப்பு நாக்கசக்கும் அன்னம்.”

2. பித்தவாதம்

“பித்தத்தில் வாதமாகில் பிடரியுங்கனுங் கையும்

குத்தது போலேயாகும் குறுகிமெய்பதனும் பின்னே”

3.ஸ்பரிசம் (தொட்டுப்பார்த்தல்)

உடல் வெப்பநிலை, சுரசுரப்பு, தோல் உலர்ந்திருத்தல், தேமல், கொப்பளம், கட்டிகள், கழலை, சொறி, சிரங்கு, படை விரணம், வீக்கம், ஊதல் ஆகியவை தொட்டுப்பார்த்தல் மூலம் அறியலாம்.

In ‘cegana vatham’ patients, general body temperature – slightly warmth but diffuse tenderness may be present in neck and upper extremities.

3. நா.

- மாப்படிந்திருத்தல், வெளுத்திருத்தல்
- வாய்நீர் வறண்டிருத்தல்
- பிளவு பட்டிருத்தல்

- ❖ புண்ணாயிருத்தல்
- ❖ சுவை மாறுபாடு

In cegana vatham patients, the tongue is normal.

4. நிறம்

- ❖ தோல்நிறம்
- ❖ சளிச்சவ்வு
- ❖ மயிர் மற்றும் நகம் முதலியவற்றின் நிறம்

In cegana vatham patients, colour of the skin appears normal.

5. மொழி

- ❖ ஒலி வேறுபாடு (Low or high pitched)
- ❖ பிதற்றல், குளறல்
- ❖ குரல் கம்மிய பேச்சு

In cegana vatham patients, no change of voice is found.

6.விழி

- ❖ கண் பார்வையின் நிலைமை
- ❖ கண் சிவந்திருத்தல், வெளுத்திருத்தல்
- ❖ கண் எரிச்சல்

In cegana vatham patients, burning sensation of eyes is present.

In aged patient acuity of vision is diminished.

7.மலம்

- ❖ மலம் என்பது உடலினின்றும் கழிகின்ற பொருள்
- ❖ நிறம், நுரை
- ❖ இறுகல், இளகல்
- ❖ மலக்கட்டு
  - ➢ Cegana vatham patients have constipation

8.மூத்திரம்

- ❖ நீர்க்குறி
- ❖ நெய்க்குறி

நீர்க்குறி

“அருந்துமாறி ரதமும் அவிரோதமாய்

அ.ˑ.கல் அலர்தல் அகாலவூன் தவிர்ந்தழற்

குற்றளவருந்தி உறங்கி வைகறை

ஆடிக் கலசத் தாவியே காதுபெய்

தொரு முகூர்த்தக் கலைக்குட்படு நீரின்

நிறக்குறி நெய்க்குறி நிருமித்தல் கடனே"

- **நோய்நாடல் நோய்முதல்நாடல் பகுதி – I**

நாம் உண்ணுகின்ற அறுசுவைப் பொருள்களும் ஒன்றுக்கொன்று வேறுபாமையடையாமலும், பசிக்குத் தக்கபடி குறைதல், அதிகரித்தல் காலந்தவறி உண்ணுதல் முதலிய குற்றங்களுண்டாகா வண்ணம் புசித்து உறங்கி, விடியற்காலத்தில் படிக பாத்திரத்தில் பெய்த நீரை ஆவிபோகாதபடி 3 ¾ நாழிகைக்குள் அதன் நிறக்குறியையும் அதில் எண்ணெய்விட்டுப் பார்த்து காணப்படுகின்ற குறியையும் கவனித்து பிணிகளின் தீரும், தீராக் குறிகளை கணிக்கலாம்.

சிறுநீரின் பொதுக்குணம்

"வந்த நீர்க்கரிஎடை மணம் நுரைஎஞ்சலென்

றைந்தியலுளவவை யறைகுது முறையே"

- **நோய்நாடல் நோய் முதல்நாடல்பகுதி – I**

இயற்கை நீர் இலக்கணம்

"மிகத் தடிப்பும் மிகத் தேறலும் இன்றெனில்

சுகத்தைத் தரும் மெய்சுபாவ நீர் நன்றே"

- **தேரன் நீர்க்குறி நெய்க்குறி**

According to theriyar, urine should be of low density and with discoloration. In cegana vatham, urine is yellow colour with low density.

நெய்க்குறி

"நிறக்குறிக் குரைத்த நிருமான நீரிற்

சிறக்க வெண்ணெய்பொர் சிறுதுளி நடுவிடுத்

தென்றுறத் திறத்தொலி யேகாதமைத்ததி

னின்ற திவலை போம் நெறிவிழியறிவும்

சென்றது புகலுந் செய்தியை யுணரே"

- **நோய்நாடல் நோய்முதல்நாடல் பகுதி – I**

நீர்நிறக் குறியால் நோயைக் கண்டு பிடித்தற்பொருட்டுச் சொல்லியிருக்கின்ற விதி பொருந்திய சிறுநீரில் ஒரு சிறியதுளி எண்ணெய் நடுவில் கையசைவினால் எண்ணெய்துளி சிதறாமல் விட்டு வெய்யிலானது அந்நீரில் படும்படி திறந்து காற்றானது அதில் வீசி அந்த எண்ணெய்த் துளி ஆடாதபடி வைத்து அச்சிறுநீரில் விடப்பட்டிருக்கின்ற எண்ணெய்த் துளியானது செல்லுகின்ற வழியில் கண்ணறிவையும்

உயிரறிவையும் செலுத்தி, அத்துளி தெரிவிக்கும் நோய் விளக்கத்தை நீ தெரிந்து கொள்ளலாம்.

"அரவென நீண்டின.்.தே வாதம்"

ஆழி போற்பரவின் அ.்.தே பித்தம்"

முத்தொத்து நிற்கின் மொழிவதென் கபமே"

- **நோய்நாடல் நோய் முதல்நாடல் பகுதி-I**

In cegana vatham patients during neikuri examination the oil spreads like snake and sometimes like ring and pearl.

ACCESSORY EXAMINATION

UYIR THATHUKKAL

Vatham

- Pranan:

  Physiological function: Inspiration and expiration responsible for sneezing coughing and belching

  Features in Ceganavatham: Not affected

- Abanan:

  Physiological function: Act with downward movement

  Features in Ceganavatham: Affected constipation present.

- Viyanan:

  Physiological function: Helps in various movements of body, responsible for sensation

  Features in Ceganavatham: Affected Restricted neck movements radiating pain in shoulder and arm with tingling sensation.

- Udhanan:

  Physiological function: Regulates the higher functions of brain. Responsible for physiological reactions like hiccough and vomiting

  Features in Ceganavatham: Not affected

- Samanan:

  Physiological function: Regulates all other vayus

  Features in Ceganavatham: Affected

- Nagan:

  Physiological function: Responsible for intelligence helps in opening and closing of eyes

  Features in Ceganavatham: Affected in aged patients. Acuity of vision is diminished.

- Koorman:

  Physiological function: Responsible for lacrimation. Helps to visualization of all things in the world.

  Features in Ceganavatham: Affected in aged patients. Acuity of vision is diminished.

- Kirugaran:

  Physiological function: Drippling of Saliva, Yawning

  Features in Ceganavatham: Not Affected

- Thevathathan:

  Physiological function: Responsible for laziness. Rotation of eyeballs

  Features in Ceganavatham: Affected (Sleeplessness present due to pain).

- Thananjeyan:

  Physiological function: Responsible for tinnitus oedema.

  Features in Ceganavatham: Not affected

Pitham

- Anar pitham:

  Physiological function: Digests all the ingested particles.

  Features in Ceganavatham: Affected

- Ranjaga pitham:

  Physiological function: Increases the blood and gives blood colour

  Features in Ceganavatham: Affected

- Saathaga pitham:

  Physiological function: Makes the work to complete what mind thinks to do

  Features in Ceganavatham: Affected neck pain and restricted movement

- Aalosaga pitham:

  Physiological function: Responsible for clear vision.

  Features in Ceganavatham: Affected in old age peoples.

- Prasaga pitham:

  Physiological function: Gives colours to skin

Features in Ceganavatham: Not affected

Kabam

- Avalambagam:

  Physiological function: Controls other 4 types of kabam

  Features in Ceganavatham: Affected (santhigam affected)

- Klethagam:

  Physiological function: Moistens the food

  Features in Ceganavatham: Not affected

- Pothagam:

  Physiological function: Helps to know the taste

  Features in Ceganavatham: Not affected

- Tharpagam:

  Physiological function: Gives cooling effect to the eyes

  Features in Ceganavatham: Affected burning sensation of eye present

- Santhigam:

  Physiological function: Gives lubrication to joints

  Features in Ceganavatham: Affected (pain in cervical region)

SEVEN PHYSICAL CONSTITUENTS OF BODY

- Saaram:

  Physiological function: Strengthens the body and mind

  Features in Ceganavatham: Affected

- Senneer:

  Physiological function: Preserves brightness, boldness, power& knowledge

  Features in Ceganavatham: Affected

- Oon:

  Physiological function: Gives structure and shape to the body.

  Features in Ceganavatham: Early stage - Not affected

  Later stage - Affected

- Kozhuppu:

  Physiological function: Responsible for movement lubricants the joint

  Features in Ceganavatham: Affected

- Enbu:

  Physiological function: Responsible to joint movements

  Features in Ceganavatham: Affected

- Moolai

  Physiological function: Present inside the bones and gives strength to the bones

  Features in Ceganavatham: Not affected

- Sukkilamor suronitham:

  Physiological function: _

  Features in Ceganavatham: Not affected

GNANTHRIYAM

- Mei:

  Physiological function: Feels the sensation of touch

  Features in Ceganavatham: Affected parasthesia present in upper limb

- Naa:

  Physiological function: Analyse the taste

  Features in Ceganavatham: Not affected

- Kan:

  Physiological function: For vision

  Features in Ceganavatham: Not affected

- Mooku:

  Physiological function: For smell

  Features in Ceganavatham: Not affected

- Sevi :

  Physiological function: For hearing

  Features in Ceganavatham: Not affected

Kanmenthiriyam

- Kai

  Physiological function: Handling the things

  Features in Ceganavatham: Affected radiating pain with tingling sensation

- Kal

  Physiological function: Walking

  Features in Ceganavatham: Not affected

- Vaai

  Physiological function: For speaking

  Features in Ceganavatham: Not affected

- Eruvaai

  Physiological function: For defaecation

  Features in Ceganavatham: Affected constipation present

- Karuvaai

  Physiological function: For reproduction

  Features in Ceganavatham: Not affected

Thinaigal

- Kurinji:

  Place : Mountain and its surroundings

  Common disease: Kabanoi liver disease are common

- Mullai:

  Place : Forest and its surroundings

  Common disease: Pitha and vatha disease liver disease and common

- Marutham:

  Place : Field and its surroundings

  Common disease: Safest place to maintain good health

- Neithal:

  Place : Sea and its surroundings

  Common disease: Vatha disease and liver enlargement are common

- Paalai:

  Place : Desert and its surroundings

  Common disease: Vatha pitha and kabha disease and common

  Most of the patients came from Marutha nilam. Patients were also reported from neithal nilam.

Paruva Kaalangal

- Kaarkaalam

  Aavani and Purattasi(August 16 – October 15)

  Kuttram- Vatham ↑ ↑Pitham ↑

- Koothirkaalam -

  Ayppasi and karthigai(October16 – December15)

  Kuttram - Vatham (-)Pitham ↑ ↑

- Munpanikaalam -

  Maargali and Thai(December 16 – February 15)

  Kuttram- Pitham (-)

- Pinpanikaalam -

  Maasi and Panguni(February 16 – April 15)

  Kuttram- Kabam ↑

- Elavenilkaalam

  Aani and Aadi(April 16 – June 15)

  Kuttram- Kabam ↑↑

- Muduvenilkaalam

  Aani and Aadi(June 16 - August 15)

  Kuttram- Vatham ↑Kabam (-)

  ↑ Thannilai valarchi

  ↑↑ Vetrunilai valarchi

  (-) Thannilai adaithal

  According to alteration of kalam (Thannilai valarchi, Vetrunilai valarchi) the disease can be diagnosed.

DIFFERENTIAL DIAGNOSIS

1.கும்ப வாதம்

"நவிலவே தோள்மீதுங் கரத்தின் மீது
நலிந்து மெத்தவாகியே நசவுண்டாகும்
கவிலவே கன்னமொடு நயனந் தானுங்
கடுத்துமே விறுவிறுப்பு மெரிவுங் காணும்
துவிலவே துடிப்பாகுஞ் சிரசு தன்னிற்
சுழற்றியே நாபிக்கீழ் வலியு முண்டாம்
அவிலவே யடிநாக்கி லழன்று காணு
மலருமே வருகும்ப வாதந் தானே"

- **யூகி வைத்திய சிந்தாமணி**

தோள்பட்டை, கை முதலிய இடங்களில் மிக்க நோயுண்டாகி அவைகளை நீட்டவும், முடக்கவும் ஒட்டாமல் நோதலும், கன்னமும் கண்ணும் கடுத்து விறுவிறுத்து எரிதலும், உடல் துடித்துத் தலைசுற்றி மிக சுரமுண்டாய் நாபியின் கீழ் வலியும் அடிநாக்கில் அழற்சியும் ஆகிய குறிகுணங்கள் இந்நோயிற் காணும்.

Mimic features	Altering features
Burning pain in shoulder joint and upper limb	Twitching over the scalp
Burning sensation in the cheek and eyes	Pain in the lower abdomen, glossitis.

2. பாணிக்கம்ப வாதம்

"மார்க்கமாய் வாய்வுமாய் மெய்நிறைந்து
வயிறுதனிற் பசியிலா தூணுமற்று
நார்க்கமாய் ஞாலத்து நடக்கையற்று
நடுக்கமாய் கையிரண்டுந் திருமிருண்டாம்
ஊர்க்கமா யுறக்கமில்லா துணர்ச்சி யற்று
உதறியே சரீர மெங்கு முலர்ந்து காணுந்

பார்க்கமாய் வாய்விட்டு அலர்த்தலாகும்
பாணிக்கம்ப வாதத்தின் பாங்குதானே"

- **யூகி வைத்திய சிந்தாமணி**

இந்நோய் உடல் முற்றிலும் வளிக்குற்றத்தை நிறைத்துப் பசித்தீயைக் கெடுத்து நடக்க முடியாமை, கை கால் நடுக்கம், கைதிமிர்தல், தூக்கமின்மை,

உணர்ச்சியின்மை, உடல் வற்றிப்போதல், வாய்பிதற்றல் ஆகிய குறிகளையும் காட்டிக் காலை மடக்க முடியாமற் கொம்பைப் போல் நிலைக்கச் செய்துவிடும்.

Mimic features	Altering features
Loss of sensation in both upper limb	Anorexia
Numbness in upperlimb, sleeplessness	Shivering of upper limbs.

3.கண்டகிரக வாதம்

"வகையாள குரலதனைப் பற்றி நொந்து
மார்போடு பிடரிதனில் வலியுண்டாகி
நுகரான சரீரமெல்லாம் நொந்த ழலாற்றி
நுணக்கமாய் சுவாசமது புறப்படாமல்
முகையான நாவாலே மூச்சு மாறி
முகத்திலே வியர்வாகி விலாநோ வுண்டாம்
பகையான வன்னத்தைப் பருகொட்டாது
பரிய கண்ட கிராகத்தின் பண்பு தானே".

- **யூகி வைத்திய சிந்தாமணி – 800**

Mimic features	Altering features
Pain in the throat, chest and occipital region	Anorexia
Breathing through mouth, backache, sweating on face	Loss of appetite.

COMPARATIVE STUDY

The word "ceganam" denotes the entire vertebra, hence ceganavatham denotes pathology in vertebra due to the derangement of vadham.

"கேளுமே கழுத்தின் கீழ் அரைக்கு மேல்"

Our body has 33 vertebrae, in which there are 7 cervical vertebrae. Spondylosis occur mostly in the lower half i.e C4, C5, C6, C7. The above line states that the pain occurs in the lower half of the cervical vertebrae and just above the lumbar region.

"கெடியான கரமிரண்டு மிகவே நொந்து"

This line indicates the radiating pain in both the upper limbs. This pain is due to the pathological changes occuring in the cervical vertebrae. There are 31 pairs of spinal nerves, in that 8 pairs are cervical nerves, having dorsal and ventral nerve roots. These nerve roots transverse through the intervetebral foramina. While passing

through the foramina compression of these nerve roots can occur due to the narrowing of the foramina. This narrowing occurs in cervical spondylosis. Because of the formation of abnormal osteophytes and ligamental calcification. This compression causes neurological dysfunction and radiating pain in the nerve plexus.

"வாளுமே சரீரமெல்லாம் கனத்திருக்கும்"

Neurological examination reveals paraesia in the affected dermatome. Gradual sensory loss in form of numbness occurs because of mural sheath compression and neurological dysfunction,

"வாலிபர்க்கு மனங்கண்ணு மயக்கமாகும்"

The vertebral artery commences from the first part of subclavian artery and passes through the foramen transversorium of the upper six cervical vertebrae. Osteophytes formed in cervical. Spondylosis compress the vertebral artery causing vertebrobasilar artery insufficiency. the blood supply to the brain is decreased due to this insufficiency resulting in gliddiness.

"ஏளுமே யிரண்டு கண்ணும் எரிச்சலுண்டாம்"

This line indicates burning sensation in the eye. Spasm of sub occipital muscles may cause a decided impediment of venous drainage from the sub occipital area via vertebral an deep cervical veins. The result is passive congestion, with consequent pressure on the sensory nerves in the area. This derangement can cause burning sensation.

"ஏற்றமாய் மலந்தானும் இறுகிக் காணும்"

Cervical sympathetic nerve is affected by neighboring irritation and damage, resulting in the nerve excitement which causes the gastrointestinal peristalsis slow down, leading to abdominal distension and constipation.

"தேளுமே கொட்டினது போல் கடுக்கும்"

In cegana vatham the pain is felt like scorpion bite. in early stage pain and rigidity is due to muscle spasm. Later ligamental calcification leads to neck stiffness.

VARMAM

Apart from the internal and external medicines,siddha system has some special therapies like varmam, yogam and kayakarpam which are distinguish to this system.Varmam refers to vital points in the body that act as energy transformers.They form centers for boosting the vital pranan flow through the intricate nadi system of the body.Nature,by its design , has protected these vital centers by placing them deep inside the body or by covering them with tissues inaccessible to normal attempts of breach.

Varmam is a holistic therapy on its own tackles the body, mind and spirit. Varmam forms a link between the body, prana and the mind. Varmam have been classified based on the type of pressure needed to apply

(i).Padu varmam-varmam due to injury
(ii).Thodu varmam-by touch
(iii).Thattu varmam-by blows
(iv).Thadavu varmam- by massage
(v).Nakku varmam-by licking
(vi)Nokku varmam-by staring

The widely used and recognized ones are the 12 Padu varmam and 96 Thodu varmams. there is less consistency with the other categories simply because of the way of application or the most awe-generating and is rarely seen practiced,as those masters who were able to do this are almost exinct.

Vital points are located over arteries,veins,nerves,joints,bony prominence, ligaments, etc.The changes occurring in the body on being hit at some specific points on the body directly or indirectly with particular force is Varmam.

By manipulating the following Varmam points,the symoptoms of Ceganavatham can be reduced

- Mudichi Varmam
- Kakkattai kaalam
- Manibantham
- Kai viral madakkuvarmam
- Kavulikaaalam

Mudichi Varmam: It is located in nape at the bony prominence of cervical region.

Kakkataikaalam: It is located at the shoulder,two finger breadth lateral to the junction of neck and head.

Manibanthagam: It is situated in dorsal aspect of wrist.

Kai viral madakku varmam: It is located in medical aspect of arm just below the shoulder.

Kavulikaalam: It is located above the web space of fingers.For ceganavatham pressure is applied in kavuli between thumb and index finger.

VAMAM THERAPY:

- Mudichi Varmam (Varma odivumuraisarasoothiram-1200)
- Kakkattai kaalam (Varma Beerangi-100)
- Manibantham (Varma Beerangi-100)
- Kai viral madakkuvarmam(Varma vilakkam)
- Kavulikaaalam(Varma soothiram-101)

MODERN ASPECT

ANATOMY OF SPINE:

The human spine as a whole is also known as vertebral column it appears straight and upright when viewed from the front are from the back. The vertebrae are stacked like wooden blocks in between the intervertebral discs. When viewed from the side it shows to gentle curves in the cervical and lumbar spine, lordotic in nature to provide maximum flexibility while providing all the strength that is required to transmit the weight of the body.

THE CERVICAL SPINE:

The cervical portion of the spine has seven cervical vertebrae. The first two vertebrae, the atlas and axis have atypical features while the remaining five has typical features.

The first cervical vertebra:

The first cervical vertebra, the atlas, is ring shaped and has four parts

1. The anterior arch
2. The posterior arch
3. Right lateral mass
4. Left lateral mass

It has five articular surfaces.

I. superior articular surfaces-connect to occipital bone.

II. Inferior articular surfaces-form lateral atlando axial joint.

III. The inner surface-form joint with dens.

The second cervical vertebra:

The second cervical vertebra,the axis, has five articular surfaces. Three surfaces connect it to the atlas and the remaining two connect it to the third cervical vertebra. The atlandoaxial joint is like wheel and axle allowing rotational movements thus allowing for a wide range of motion. At times the dens which are realy the vertebral body of c1 separates from c2 and forms separate os odontoideum.

Third to seventh cervical vertebrae:

Remaining five cervical vertebrae are similar in shape. The vertebral bodies are small and the canal large in comparison with the thoracic and lumbar spines. The spinous processes are small and bifid except C7. Bifid spinous processes allow more extension without interfering with each other. The intervertibral joint are horizontal and transmits the weight of the head. Each transverse process is composed of two tubercles. The anterior tubercle is the representative of rib and at times a cervical rib is actually seen. The posterolateral corner of the upper surface of lower vertebra is elevated and is called the uncus or uncinate process. The uncus is not found inquadrupends. It is only found in those who have to support their head. The uncus forms a joint with the lower surface of upper vertebral body called the neurocentral joint of luschka. The uncus actually is a part of the arch and there is no disc tissue in that joint. The spinal canal is relatively broad. The average value is 17 to 18 mm in normal adults but is under 15 mm is case of myelopathy. The smallest canal is found in Japanese people being at times less than 13 mm.

The articular processes of facet joints do not have uniform direction. At times the superior articular process is process is positioned more anteriorly then the vertebral foramen and the canal at this place becomes narrow causing radiculopathy. The position can easily be observed on lateral X-ray of the cervical spine.

THE INTERVERTERAL DISC

The vertebral disc is thicker in infants than in adults. At birth the discs occupy half the length of the cervical spine. In adults the length is one third of the cervical spine and after age of 50 years it is reduced further. The nucleus changes its shape to accommodate the changes due to motion. It bears loads during movements of the spine. The dense collagen fibers of the annulus are running vertical in the front and are strong. Posteriorly they run horizontally and are prone to be fissure.

THE LIGAMENTS OF CERVICAL VERTEBRAE:

There are two longitudinal ligaments,

1. Anterior longitudinal ligaments – covers the anterior surface of the vertebral body and its lateral margins sptead under the longus colli muscles.

2. posterior longitudinal ligaments – composed of two layers

- Superior
- Deep

Both layers unite firmly in the central part and laterally the separate and the superficial layer invests the dura and the nerve root. The periosteum is lying under the ligaments.

The ligamentum flavum varies slightly in its attachment in comparison to lumbar spine. It covers the anterior one-third of upper lamina and posterior one-third of lower lamina. With this arrangement the ligament buckles in during extension of the neck.

The interspinous ligament in the cervical spine is less well developed and week. The supraspinous ligament is extremely well developed and forms the ligamentum nuchae.

THE BONY CERVICAL SPINAL CANAL:

The conus medullaris ends at the lower border ofL1 vertebra. Beyond that the dural sheath contains only the cauda equine. The shape of the cervical canal varies significantly from C1 to C7. The canal is almost round at C1 and slowly transforms into trifoliate pattern at C7. The sagittal diameter of the canal is always measured to give an indication of the size of the canal. It is measured from the posterior surface of the vertebral body to the junctional point between the lamina and the spinous process. This point is not always easy to define and one has to resort at times to tomography to define this point. A canal of 20 mm is capacious at C1 measurement from 17 to 14 mm are normal. A sagittal diameter of 13 mm at C5 is on the border line. A canal of less than 13mm diameter is definitely narrow. The cervical spinal canal is many times known to be narrow in patients with cervical spondylotic myelopathy.

SPINAL CARD:

The spinal cord in the cervical region is thick with well developed grey matter and is oval in shape its blood supply comes from one anterior and posterior spinal arteries. Branches of these vessels which form the Coronal artery surround the card. The central artery, a branch of anterior spinal artery, enters the cord from the anterior fissure. Additional radicular arteries come from vertebral artery supply blood to this network. The function of the card is compromised either by direct mechanical

pressure or vascular insufficiency. Compression anteriorly comes from prolapsed disc, osteophytes or ossification in the posterior longitudinal ligament. posteriorly the cord can be compressed by the ligamentum flavum. Fibrous around the root and pathological anchoring of the denticulate ligaments can cause further the compressive damage to the cord. when the career developmentally narrow and the space around the cord is compromised any friction occuring during daily activities can cause damage to the cord. the shape of the cord is oval and the shape of the canal is triangular resulting in crowding of nervous tissue posterolaterally in the canal.

THE NERVE ROOTS

of 31 pairs of nerve roots the first and the last nerve roots are not available on the surface for examination. the first cervical nerve root is entirely motor without sensory branches and it serves the suboccipital muscles. the posterior branch of secondary nerve is thick and is called the Great occipital nerve. the first two cervical nerves (C1 and C2) do not come out through the intervertebral foramina like the rest but they come out throw a narrow fissure between occiput and C1 posterior arch and C1 / C2 posterior arches. they are frequently compressed in hyperextension injuries.

Important nerve root supply to muscles:

NERVE ROOT	**SUPPLY TO MUSCLES**
3rd nerve root	Pectoralis muscles
4rd nerve root	Diaphragm
5rd nerve root	Deltoid muscles
6rd nerve root	Muscles of thumb
7rd nerve root	Muscles of middle finger
8rd nerve root	Muscles of ring and little finger

In the lower cervical spine sometimes the discrepancy can be found When the seventh cervical road leaves through the foramina between 5th and 6th cervical vertebra. Pathology in this region can cause radiculopathy in both 6th and 7th cervical roots. osteophytes without Disc prolapse are known to produce pure motor weakness with atrophy without pain and without sensory disturbance and needs to be differentiated from progressive spinal muscular atrophy.

The vertebral artery enters the transverse foramina of the sixth cervical vertebra. Presence of osteophytes on the joints of luschka can compromise the cana width. Being in the foramen at this level the vessels cannot slide laterally resulting in stricture in the vessels. In elderly with established spondylotic changes the cervical spine is shortened and the vertebral artery is forced to persue a tortuous course and it can then cave into the vertebral body. Two or three radicular arteries supply the spinal cord. Usually they enter the spinal cord at the level of 6th cervical vertebra. The artery usually runs on the ventral side of the nerve root and it can be compressed much earlier by the osteophyte than the Nerve Root.

THE MUSCULATURE

The musculature of the neck is broadly divided into three groups the three groups are:

1. muscles involved in the movements of head and neck
2. muscles involved in the movements and suspension of arms
3. muscles involved in the movement and suspension of thoracic cage

When a load is applied to the arms, say, for example, while lifting a weight to be placed on the head the weight of the load is transferred to the cervical spine through the muscles of the arms and hence this group of muscles deserve special attention. raising something by the hand means raising it by the cervical spine. this explains why cervical spine degenerates early in workers doing heavy manual work.

To hold the head in proper position it is essential to have a delicate balance of contraction and relaxation among neck muscles. the free Nerve endings in the cervical spinal musculature is disproportionately large and their discharges control not only the head position but also controls the posture of the whole body. the small suboccipital muscles play a vital role in this function and the concentration of spindle density in this muscles is much higher than the density in the lumbrical muscles of the hand.

THE LIGAMENTS:

The following biochemical properties are observed in the ligaments:

Resistance:

Ligaments offer resistance to stretch (tension)

Relaxation:

On continued stretch there is gradual relaxation in tension in the ligaments

Creep:

Gradual lengthening in the ligament during stretch manoeuvres

Elastic deformation:

The creep of gradual lengthening can be reversed totally on elimination of stretch suggesting that there has been no structural damage sustained to the ligament during stretching. It is seen best in the ligamentum flavum and very little in scar tissue.

Plastic deformation:

The ligament does not return to normal on elimination of stretch. This property can be clinically used to stretch stiff ligaments and muscles during postoperative period.

Break point:

if the stretch is continued after plastic deformation the ligament breaks as the stress becomes more than the inherent capacity of the viscoelastic property of the ligament. The spine as a whole is an excellent example of viscoelastic properties of ligaments and demonstrates creep or lengthening with continued stress.

The spine is elastic but there is a difference between a metallic spring and the spine composed of bone, cartilage, muscles and joints. Unlike metallic spring which exhibits linear deformation, the spine exhibits non linear deformation.

FACTOR INFLUENCING STABILITY IF THE SPINE:

The factor influencing stability in the spine are:

1. Passive stability
    - shape of the vertebral bodies
    - shape of the facets
2. Dynamic stability
    - Linking of viscoelastic ligaments
3. Active stability
    - Deep postural muscles
4. Hydrodynamic stability
    - Turgid nucleus distributes load uniformly

DEVELOPMENT:

The skin of the neck is derived from cervical dermatomes which arise from the second to the sixth cervical segments.

The sternocleidomastoid, strap muscles and trapezius originate from cervical myotomes.

MUSCLES OF NECK:

- Sterno-cleidomastoid muscle.
- Trapezius muscle.
- Platysma muscle.
- Splenius capitis muscle.
- Levator scapulae muscle.
- Scalenus medius muscle.
- Scalenus anterior muscle.

MAJOR BLOOD VESSLES:

- Common Carotid artery
- Internal & external carotid artery
- External carotid artery
- Internal Jugular Vein
- External Jugular Vein

NERVES:

- glassopharyngeal nerve
    - tympanic nerve
    - lesser petrosal nerve
    - carotid branch pharyngeal branch
    - muscular branch
    - tonsillar branch lingual branch

- vagus nerve
- accessory nerve
- hypoglossal nerve

MOVEMENTS OF THE CERVICAL SPINE

The cervical spine is the most mobile segment of the whole spine. Maximum range of motion is possible in this portion of the spine. Therefore it is also subject to significant injury being extremely mobile. The range of motion and its reduction with increasing age has been described in the section on age related changes in the cervical spine. The spine as a whole and particularly the cervical spine is made of several segments. Thus there are eight motion segments related to the cervical spine. Any motion simply cannot occur in one given motion segment. When a movement has to occur all motion segments cooperate to produce a smooth gliding coordinated motion.

Movements of the cervical spine

1. Flexion and extension
2. Lateral bending
3. Rotation

It is important to understand the different between one motion and range of motion. In range of motion two parameters are involved and hence range of motion is different from motion in one movement. All motions have multiplanar coupling, e.g. ratio of rotation in rotation in lateral bending varies at different levels depending on orientation of facets. Inclination of facet joints at 45 to 80 degrees with respect to the horizontal plane of intervertibral disc causes simultaneous sliding and rotation. The orientation of facet joints is partly responsible for this multiplaner coupling. It has been shown that at the level of C3 and C4 the superior articular facets are displayed posterolaterally and it correlate well with the pattern of cervical movements.

AXIAL ROTATION:

Axial rotation to the tune of 24 degrees is possible at occiput/ C1 junction and 46 degrees at C1 /C2 Junction. The lower cervical spine is locked in Flexion and open in extension. there is no rotation in flexion but in neutral position or extension it can given 14 degrees rotation.

FLEXION/ EXTENSION

Total extension is relatively less than total flexion. Total flexion possible in 53 degrees and total extension is 38 degrees with range of motion in flexion/ extension in normal adults below the age of 50 years being 130 degrees in male and slightly more in females.

LATERAL BENDING

There is very little lateral bending in the upper cervical spine. all the lateral bending is done in the lower cervical spine. the range of motion in males is 88 degrees and in females about 5 degrees more than males in normal adult.

CLINICAL BIOMECHANICS OF CERVICAL SPONDYLOSIS:

Spondylotic changes defined as a condition of progressive degeneration that beings in an intervertebral disc and leads to changes in the apophyseal joints and related ligament- capsular tissue of the spine. The degeneration initiated in the intervertebral disc progress to pathology events leading to growth of bone at the margins of vertebrae. fibrosis at first starts in the annulus leading to delamination in the laminated structure and finally causing focal disruption. the progression of fibrous tissue extended to the nucleus leading to loss of annular nucleus demarcation. vertebral bodies then become rough and start showing osteophytes. It is now believed that delamination in the annulus is the most important event in the initial pathological changes in spondylosis.

STRUCTURAL DEGENERATION IN THE INTERVERTEBRAL DISC

When the cervical spine is subjected to bending forces, one side of the disk is compressed and the other side is subjected to tension. During tortional movements as in flexion rotation or extension rotation there are shear stresses in the horizontal as well as axial planes of the annulus. The intervertebral disc is obviously subjected to various patterns of loading in different circumstances. The forces created are:

1. Generation of tensile strength in the annulus
2. Friction between various lamellae of the annulus and
3. Increased pressure within the nucleus.

Load has to be observed and energy has to be dissipated. this is done by tension and friction in the annulus and free water shift in the nucleus. in studying the mechanics of functioning of intervertebral disc two things are important

1. One is the speed of load and

2. The other is the acceleration of speed

In normal subjects there is a definite and constant gradient descending down along the spine between the centre of each vertebra for both speed and acceleration. in patients with abnormal moments like athetoid moments a sudden level of increase in

both speed and acceleration occurred at certain segments during flexion/extension moments and the cervical spine displayed a large range of motion than normal subjects.

This knowledge has important clinical significance. A spine which is continuously subjected to motion with increased range, speed and acceleration for a period of more than 20 years results in reduction of mechanical strength in the intervertebral disc. The sequelae of such abnormal persistent load on the spine causes structural degradation starting in the annulus fibrosus just as it occurs in disc degeneration at a later age.

Mechanical overuse of spine has been studied in animal models by producing repeated flexion/extention motion in the cervical spine. The intervertebral disc was examined between 15 and 70 days of continuous cyclic loading. Structural degradation was most commonly encoundered at C7/C8 level and in the margins of adjacent vertebral bodies. The annulus was delaminated and focally disrupted. There was early osteophyte formation at the anterior margin of C7 vertebra.

Increasing the load in the cycles resulted in more advanced degradation and degeneration similar to what is seen with spondylosis. Irrespective of age of the subject disc degeneration advanced with increasing load on the disc. At least experimentally, overuse appeared to produce fatigue failure in the structures of the intervertebral disc.

CERVICAL SPONDYLOSIS

The term cervical spondylosis describes chronic degenerative lesions of single or multiple intervertibral discs with formation of osteophytes in related vertebral bodies. Cervical spondylosis is a leading cause of musculoskeletal disability in humans. The sequence of disc degeneration leads to the clinical syndrome of cervical pain, radiculopathy and myelopathy. The The aetiology was thought to be related to aging process and or mechanical overload applied to the spine. However the fact that an unexpectedly high incidence of early spondylosis has been seen in patients with thetoid cerebral palsy and other such disorders precludes age related process as the only pathology. Accelerated segmental hypermobility sets in very early degenerative changes in the intervertebral disc.

Cervical spondylosis is more common in the elderly where advanced changes leads to disaling pain and paresis the number of elderly people in the world is growing at an unprecedented rate.

CERVICAL SPONDYLOSIS CAUSES

The bones and protective cartilage in your neck are prone to wear and tear that can lead to cervical spondylosis. Possible causes of the condition include:

Bone spurs

These overgrowths of bone are the result of the body trying to grow extra bone to make the spine stronger. However, the extra bone can press on delicate areas of the spine, such as the spinal cord and nerves, resulting in pain.

Dehydrated spinal discs

Spinal bones have discs between them, which are thick, pad-like cushions that absorb the shock of lifting, twisting, and other activities. The gel-like material inside these discs can dry out over time. This causes your bones (spinal vertebrae) to rub together more, which can be painful. According to the Mayo Clinic, this process can begin around age 40.

Herniated discs

Spinal discs can develop cracks, which allows leakage of the internal cushioning material. This material can press on the spinal cord and nerves, resulting in symptoms such as arm numbness and pain that radiates down an arm.

Injury

Had an injury in neck, such as during a fall or car accident, this can accelerate the aging process.

Ligament stiffness

The tough cords that connect your spinal bones to each other can become even stiffer over time, which affects your neck movement and makes the neck feel tight.

Overuse

Some occupations or hobbies involve repetitive movements or heavy lifting, such as construction work. This can put extra pressure on the spine, resulting in early wear and tear.

Risk factors

The greatest risk factor for cervical spondylosis is aging. Cervical spondylosis often develops as a result of changes in your neck joints as you age. Disc herniation, dehydration, and bone spurs are all results of aging.

Factors other than aging can increase your risk of cervical spondylosis. These include:

- Neck injuries
- Work-related activities that put extra strain on your neck from heavy lifting
- Holding your neck in an uncomfortable position for prolonged periods of time or repeating the same neck movements throughout the day (repetitive stress)
- Genetic factors (family history of cervical spondylosis)
- Smoking
- Being overweight and inactive

SYMPTOMS OF CERVICAL SPONDYLOSIS:

Most people with cervical spondylosis don't have significant symptoms. If symptoms do occur, they can range from mild to severe and may develop gradually or occur suddenly.

- One common symptom is pain around the shoulder blade. Some complain of pain along the arm and in the fingers. The pain might increase when:
  - Standing
  - Sitting
  - Sneezing
  - Coughing
  - Tilting your neck backward
- Another common symptom is muscle weakness. Muscle weakness makes it hard to lift the arms or grasp objects firmly.

Other common signs include:

- A stiff neck that becomes worse
- Headaches that mostly occur in the back of the head
- Tingling or numbness that mainly affects shoulders and arms, although it can also occur in the legs
- Symptoms that occur less frequently often include a loss of balance and a loss of bladder or bowel control. These symptoms warrant immediate medical attention.

TESTING AND DIAGNOSING

Making a diagnosis of cervical spondylosis involves ruling out other potential conditions, such as fibromyalgia. Making a diagnosis also involves testing for movement and determining the affected nerves, bones, and muscles. Your primary care physician may treat your condition or refer you to an orthopedic specialist, neurologist, or neurosurgeon for further testing.

PATHOPHYSIOLOGY:

The intervertebral disk is composed of an inner nucleus pulposus and an outer annulus fibrosus. The nucleus consists of a mesh of type II collagen and an extracellular matrix of proteoglycans that are hydrophilic, maintain a high water content, and resist compressive forces. The annulus is comprised of a concentric series of interwoven fibrous lamellae that provide tensile strength to the disk. They attach to the anterior and posterior longitudinal ligaments and the superior and inferior endplates. As individuals age there is a characteristic degenerative cascade that develops in the intervertebral disks. Typically, in the third decade there is a change in the proteoglycan content leading to reduced levels of condrotin sulphate and increased levels of keratin sulphate. These changes diminish the disks ability to maintain its normal fluid concentration and leads to a decreased ability of the nucleus to resist normal compressive [forces. This places additional stress on the outer annular fibers. The disk then looses a portion of its normal height. This causing buckling of the ligamentum flavum, facet joint capsules, and annulus into the spinal canal and neuroforamen. This increases the resultant loading of the facet joints and leads to facet joint degeneration. Additional bone spurs can form and cause further narrowing of the spinal canal and foramen.

One of the most common manifestation of cervical disk disease is a disk herniation. Disk herniation can be categorized as soft or hard. A soft disk herniation is the result of a disruption of the outer anular fibers with protrusion of the inner nucleus material causing compression of the exiting nerve roots. Soft disk herniations are most commonly seen in patient between 30 years and 50years of age. A hard disk herniation is the result of osteophyte formation or calcification of disk material and typically causes chronic symptoms in patients greater than 55 years of age. Soft disk herniations can be further categorized as a bulge, protrusion, extrusion or sequestration. A disk buldge is a caused by the nucleus pushing on the annulus but without any distribution of the annular fibers. A protrusion is a small defect in the outer annular fibers with a portion of the nucleus dis[placed outside the annulus. The base of the protrusion is wider than the material displaced beyond the borders of the annulus. A disk extrusion consists of further displacement of the nucleus beyond the borders of the annulus where the diameter of the displaced material is greater than at the base. A sequestered disk herniation is a completly live piece of disk that has separated from the reminder of the disk.

In the cal spine the nerve rootsexit above the pedicle as compared to the lumbar spine where the nerve roots exit below the pedicle of the same number. For example the c6 nerve root will exit above tec6 pedicle at the c5-c6 disk space. The c8 nerve root exits at the c7 –T1 disk space.

Axial neck pain can be caused by muscular or ligamentous deconditioning or injury. This can result from poor posture, fatigue, stress, and a poor ergonomic environment. Degenerative disk disease can also directly cause axial neck pain. The outer annular fibers are innervated by the sinuvertebral nerve, which is composed of fibers of the ventral nerve root and sympathetic plexus. Studies have described a reproducible pattern of axial neck pain associated with provocation discography at each cervical disk level. The facet joints can also contribute to axial neck pain through their innervations from the medial branches of the ventral rami.

Cervical radiculopathy most commonly occurs due to compression of the exiting nerve root in the intervertebral foramen either due to disk herniation, osteophyte formation, or loss of disk height and subsequent foraminal height narrowing. Other known causes of cervical radiculopathy comprise of the normal blood supply to the nerve root and chemical radiculitis. A constriction of the venous blood flow from the nerve root can lead to oedema and fibroses of the nerve root.

Various neurogenic and non-neurogenic chemical pain mediators have also been reported to be released from the degenerative disk that can result in radicular symptoms. There include substance P, somatostatin, vasoactive intestinal peptide, calcitonin gene-related peptide, angiotensin II, bradykinin, serotonin, histamine, acetylcholine, and prostaglandin E1 and E2.

PHYSICAL EXAMINATION

1. Spurling sign

Radicular pain is exacerbated by extension and lateral bending of the neck toward the side of the lesion. Which result in further foraminal compromise.

2. Lhermitte's sign

The generalized electric shock sensation is associated with neck extension.

3. Hoffman sign

Reflex contraction of the thumb and index finger occurs in response to nipping of the middle finger. This sign is evidence of an upper motor neuron lesion. A Hoffman sign may be insignificant if present bilaterally.

4. Axial compression test

Pain that is elicited by axial compression.

5. Shoulder abduction test

Relief of cervical radiculopathy by abduction.

6. Valsalva manouevre

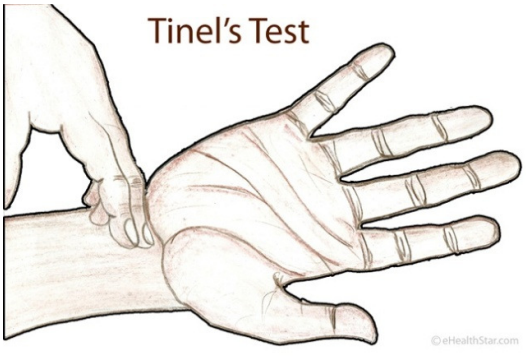
Increase the radicular symptoms.

7. Phalynx wrist flexion test

Full passive flexion of the patients wrist for 30-60 seconds and looking for reproduction or worsening of worsening of finger dysthesiasis

8. Tinel's sign

Elicited by tapping over the median nerve at the carpal tunnel.



9. The elbow flexion test

Fully flex the elbow and observe for ulnar nerve distribution.

10. Adson's test

Turns his head to the involved side, raises the chin and holds a deep inspiration and while the ipsilateral radial pulse is palpated with the arm slightly abducted from the side if pulse diminishes test positive for thoracic outlet syndrome.

Complications

1. Pseudo arthrosis
2. Graft displacement.
3. Neurological injury
4. Spastic gait
5. Quadriplegia
6. **Injury to other structures**.
    - Recurrent laryngeal Nerve.
    - Superior laryngeal Nerve.
    - Carotid artery.

DIFFERENTIAL DIAGNOSIS

1. **Thoracic outlet syndrome**

There is compression of lower trunk of brachial plexus by an anomalous band that connects the transerve process of C7 within the first rib. Neurologic deficit include weakness of intrinsic muscles of the hand and diminished sensation over the palmar aspect of fourth and fifth digits.

2. **Brachial plexus and nerve injury**

Pain from injury to the brachial plexus or peripheral nerves can be confused with pain of neck origin. Infiltration of peripheral nerves by neoplasm may occur in lower trunk of brachial plexus and produce shoulder pain that radiates down the arm. There is numbness of the fourth and fifth fingers with weakness of intrinsic muscles of the hand supplied by ulnar and median nerves.

3. **Refered pain**

Cardiac ischemia causes left sided brachial neuralgia. In those patients, diagnosis depends on the history, examination and abnormal findings in ECG. Sub – diaphragmatic lesions cause right sided pain.

Gall bladder lesions causes right sided brachial neuralgia. The diagnosis depends upon the history examination and investigations.

4. **Syringobulbia:**

Dissociated sensory loss on the face, palatal palsy, Horner's syndrome, nystagmus, Kyphoscoliosis, pescavus and spina bifida are then found.

5. **Syringomyelia:**

Long history of neck and arm pain, depending on the site of the syrinx, ascending or descending spinal pathways may be affected which can lead to a spastic paraparesis or sensory deficit in the upper and lower extremities pressure on the anterior horn cells can lead to fasciculation and atrophy of the upper limb muscles.

In the lower extremities hyperflexia in the legs and extensor plantar responses are common. Charcot joint in the shoulders, elbows or knees are common in advances cases.

6. **Tumours of the spinal canal**

(a)Extra dural or epidural tumour

Commonest extra dural tumours are the spinal metastasis. The symptoms are local pain, radiating pain which is exacerbated by coughing, sneezing or straining pain and local tenderness often proceed.

(b) Intra dural Tumours:

(i) Intra medullary tumours:

Dissociated sensory loss in the segments of tumour origin and spring of posterior column sensory function. Later spinothalamic tracts may be involved. The sacral segments may be spared. Atrophy in the appropriate segments due to anterior horn cells involvement.

(ii) Extra medullary tumours: (Meningiomas neurofibroma)

Local back pain, sensory loss below the level of the pain, weakness and bladder and bowel dysfunctions.

7. Tabesdorsalis:

Fleeting and respetitive shooting pains occurring mostly in the legs. Loss of reflexes in the legs, impaired position and vibration sense gives severe ataxic gait. Romberg's test is positive. Aygyll Robertson pupils constitute a typical tabetic facies.

8. Epidural abscess:

This condition can occur as a complication of operation or lumbar puncture. Spinal osteomyelitis cause abscess formation Unexplained fever and mild spinalache, later radicular pain occurs. As the abscess expands it causes and compression with transverse and usually complete transaction syndrome.

IMAGING TESTS

- X-rays can be used to check for bone spurs and other abnormalities.
- A CT scan can provide more detailed images of your neck.
- An MRI scan, which produces images using radio waves and a magnetic field, helps your doctor locate pinched nerves.
- In a myelogram, a dye injection is used to highlight certain areas of your spine. CT scans or X-rays are then used to provide more detailed images of these areas.
- An electromyogram (EMG) is used to check that your nerves are functioning normally when sending signals to your muscles. This test measures your nerves' electrical activity.
- A nerve conduction study checks the speed and strength of the signals a nerve sends. This is done by placing electrodes on your skin where the nerve is located.

MANAGEMENT:

1.Medication:

a) Analgesic and muscle relaxant

b) Corticosterone injection

2. Physiotheraphy : To relieve pain and enchance movement of the neck.

3. Conservative methods

(i) Cervical Traction:

Vertebral traction should be the first choice of pain relief for patients suffering nerve root pain. Intermittent sustained traction is carried out after careful positioning has localized the involved segment in such cases the treatment atleast once a day is essential prolonged pain relief will take several days to obtain.

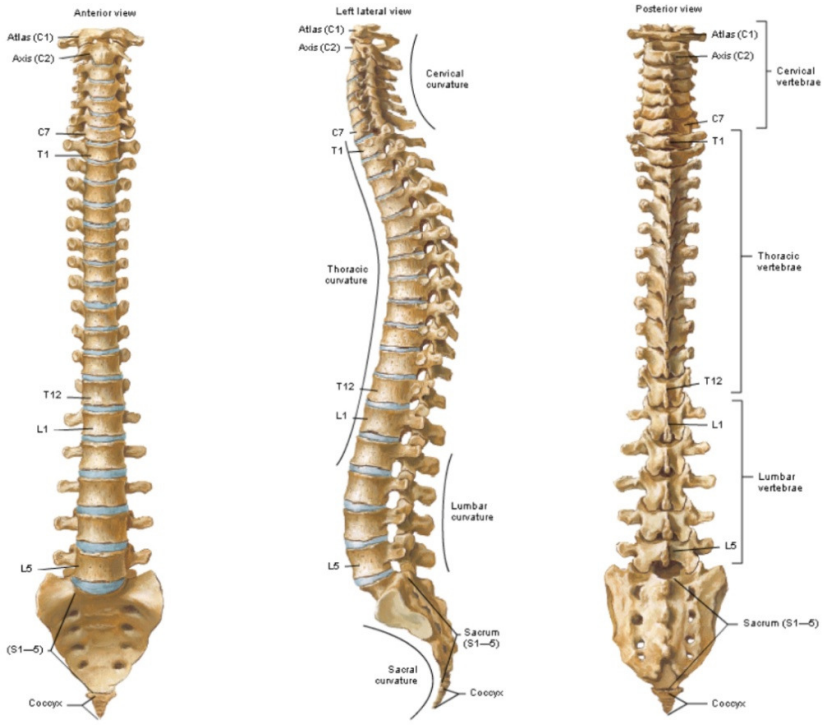
Cervical traction provides positive patient response and can relieve the pain associated with certain neck disorders. It applies a stretch to muscles, ligaments and tissue components of the Cervical spine. It provides relief by promoting.

Seperation of the intervertebral joint space which contains the disc and may reduce a "bulge" or impingement of structures for use in the foramen. It is not indicated for use in condition of instability such as with "Whiplash" injury. It is most commonly used when the patient is in the supine position with the neck placed at 20^0-30^0 of flexion. Using traction in this position helps stretch the posterior neck muscles and facilitate intervertebral seperation, Which relieves pressure that may be pinching nerves, therefore promoting muscle relaxation and intervertebral separation.

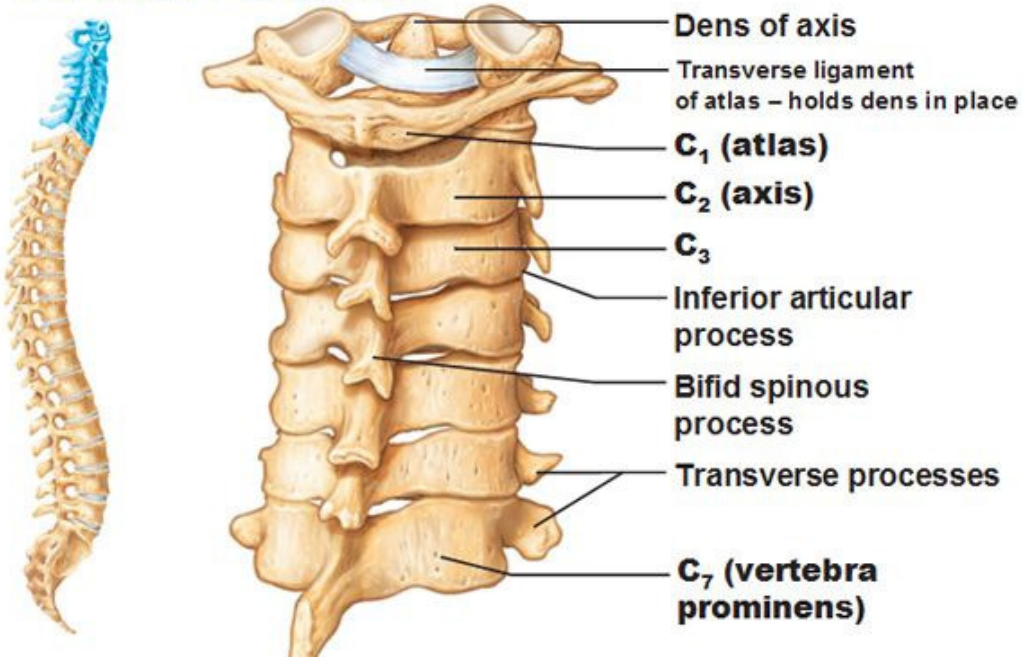
(ii) Cervical collar/ Cervical Bracelet:

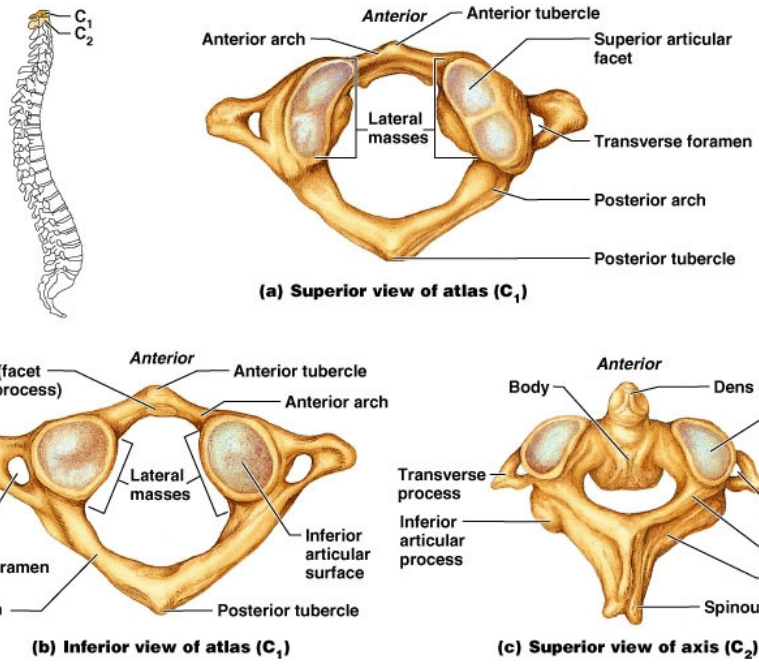
Cervical collar are advised to wear temporary collar for day time to restrict movement and a soft collar for support at night. A patient who is given a collar should be advised that the restriction in neck movement will alter other proprioception, for example he will need to take care in the dark or on entering darkened rooms when he may lose his balance. A patient wearing a collar should not drive because judgement of relative distance will be impaired. In the case of vertebrobasillar insufficiency cervical collar may be advised to the suffers according to the severity.

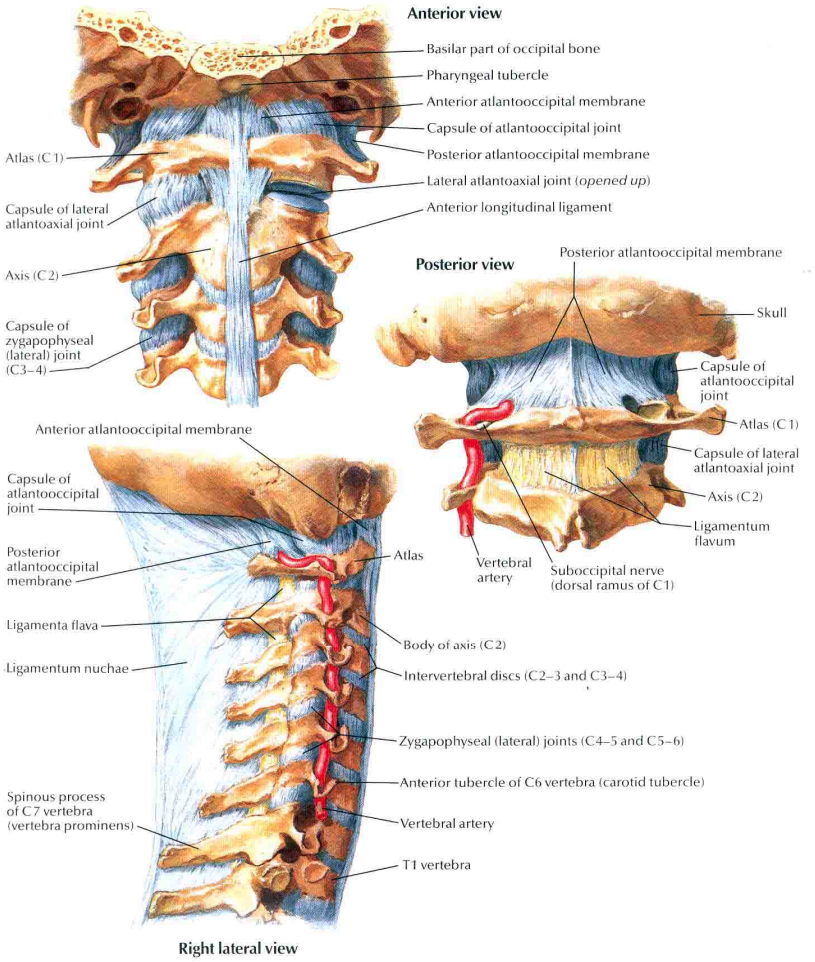
VERTEBRAL COLUMN

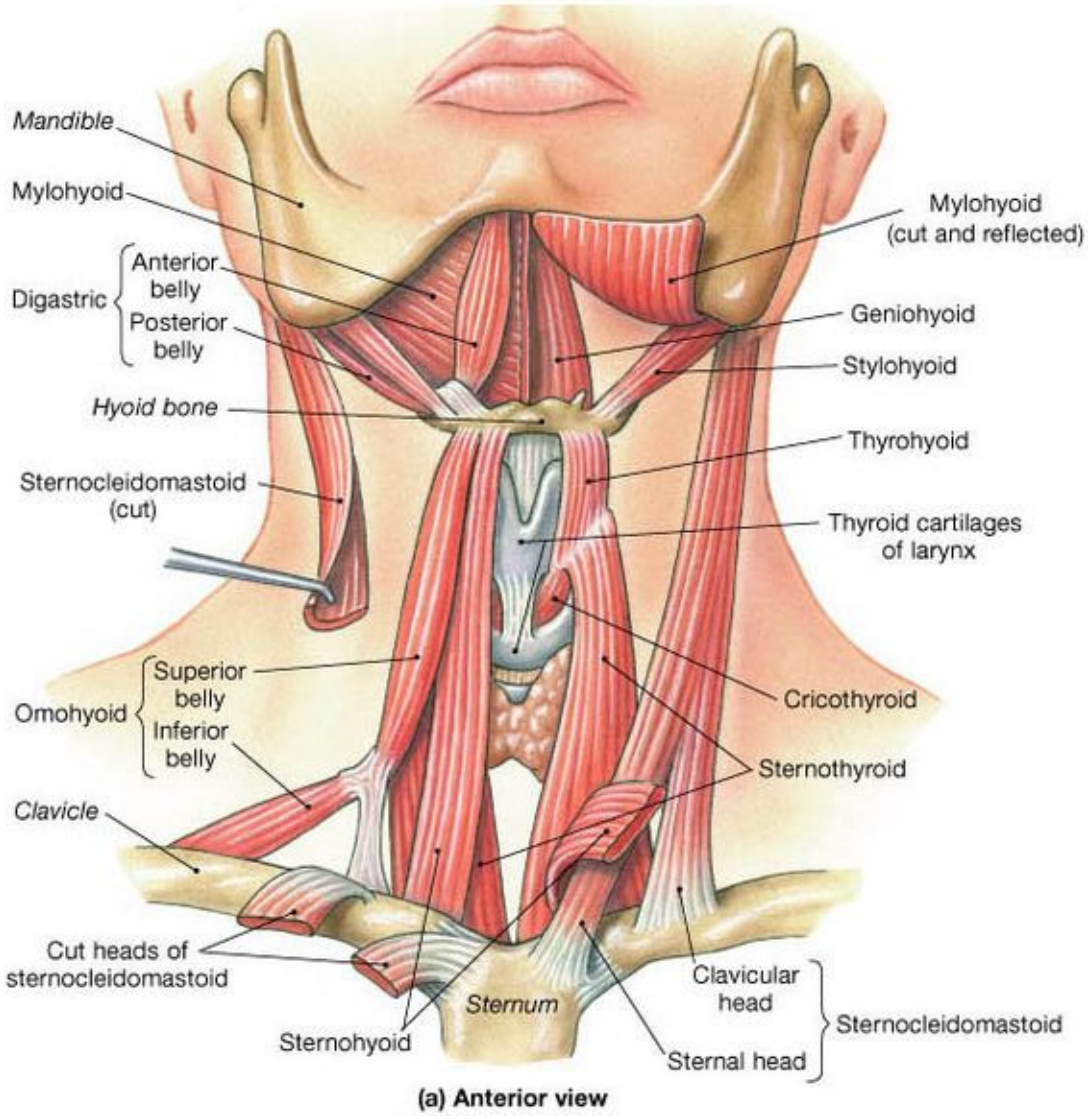


Cervical Vertebrae

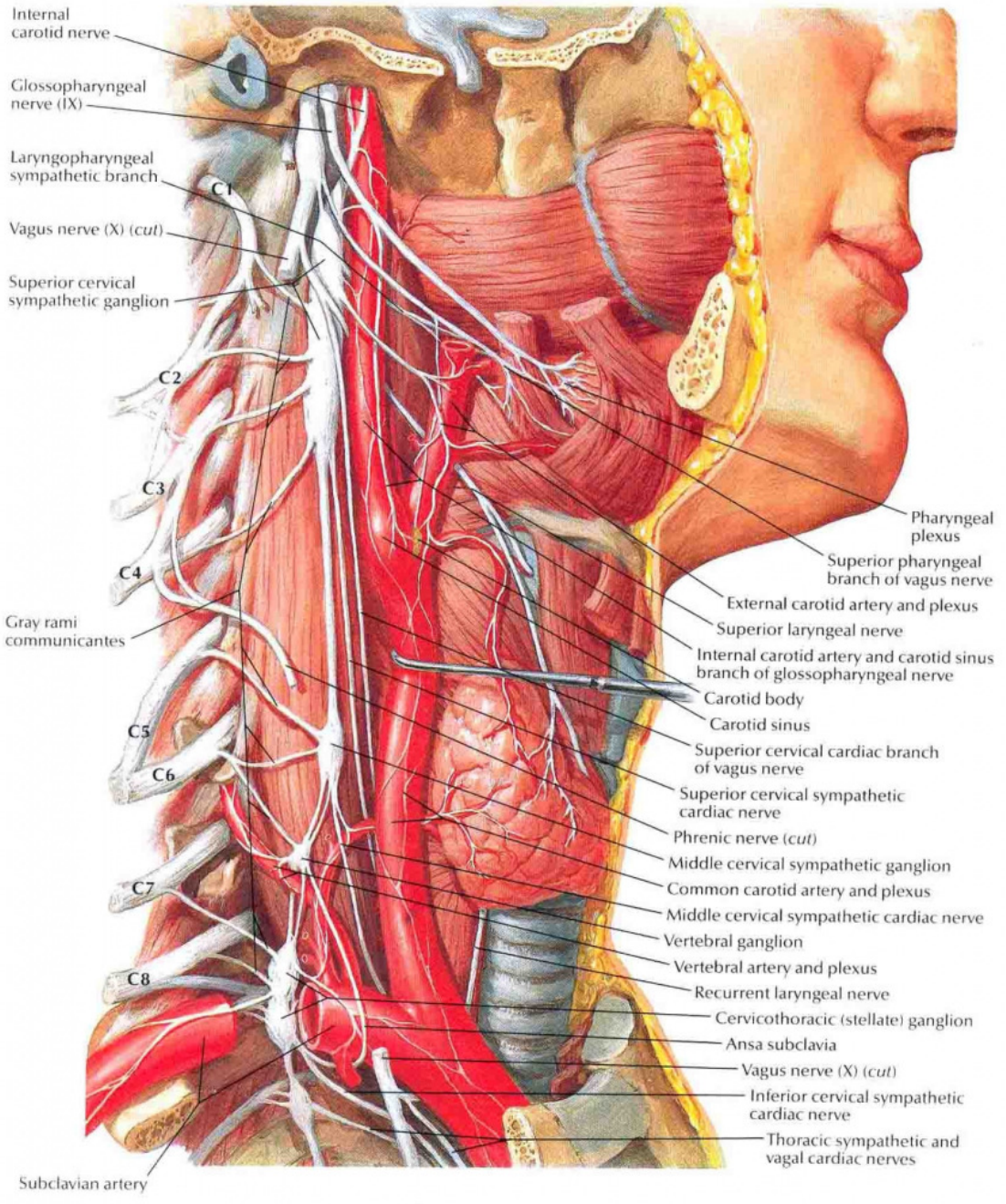



C1
C2
Anterior
Anterior tubercle
Anterior arch
Superior articular facet
Lateral masses
Transverse foramen
Posterior arch
Posterior tubercle
(a) Superior view of atlas (C1)
Anterior
Fovea dentis (facet for odontoid process)
Anterior tubercle
Anterior arch
Lateral masses
Transverse process
Transverse foramen
Posterior arch
Inferior articular surface
Posterior tubercle
(b) Inferior view of atlas (C1)
Anterior
Body
Dens (odontoid process)
Superior articular surface
Transverse process
Transverse foramen
Inferior articular process
Pedicle
Lamina
Spinous process
(c) Superior view of axis (C2)


Anterior view
Basilar part of occipital bone
Pharyngeal tubercle
Anterior atlantooccipital membrane
Capsule of atlantooccipital joint
Posterior atlantooccipital membrane
Lateral atlantoaxial joint (opened up)
Anterior longitudinal ligament
Atlas (C1)
Capsule of lateral atlantoaxial joint
Axis (C2)
Capsule of zygapophyseal (lateral) joint (C3–4)
Posterior view
Posterior atlantooccipital membrane
Skull
Capsule of atlantooccipital joint
Atlas (C1)
Capsule of lateral atlantoaxial joint
Axis (C2)
Ligamentum flavum
Vertebral artery
Suboccipital nerve (dorsal ramus of C1)
Anterior atlantooccipital membrane
Capsule of atlantooccipital joint
Posterior atlantooccipital membrane
Atlas
Ligamenta flava
Ligamentum nuchae
Body of axis (C2)
Intervertebral discs (C2–3 and C3–4)
Zygapophyseal (lateral) joints (C4–5 and C5–6)
Anterior tubercle of C6 vertebra (carotid tubercle)
Spinous process of C7 vertebra (vertebra prominens)
Vertebral artery
T1 vertebra
Right lateral view



(a) Anterior view


Internal carotid nerve
Glossopharyngeal nerve (IX)
Laryngopharyngeal sympathetic branch
C1
Vagus nerve (X) (cut)
Superior cervical sympathetic ganglion
C2
C3
C4
Gray rami communicantes
C5
C6
C7
C8
Subclavian artery
Pharyngeal plexus
Superior pharyngeal branch of vagus nerve
External carotid artery and plexus
Superior laryngeal nerve
Internal carotid artery and carotid sinus branch of glossopharyngeal nerve
Carotid body
Carotid sinus
Superior cervical cardiac branch of vagus nerve
Superior cervical sympathetic cardiac nerve
Phrenic nerve (cut)
Middle cervical sympathetic ganglion
Common carotid artery and plexus
Middle cervical sympathetic cardiac nerve
Vertebral ganglion
Vertebral artery and plexus
Recurrent laryngeal nerve
Cervicothoracic (stellate) ganglion
Ansa subclavia
Vagus nerve (X) (cut)
Inferior cervical sympathetic cardiac nerve
Thoracic sympathetic and vagal cardiac nerves

MATERIALS AND METHODS

The clinical study on Ceganavatham was carried out in the post graduate sirappu maruthuvam department of Government siddha medical college and Palayamkottai In this study 40 patients (who are selected by inclusion and exclusion criteria) were treated as OP and IP patients.

Selection of the patients:

Age:

20 years to 65 years

Sex:

Male and Female

Clinical Findings:

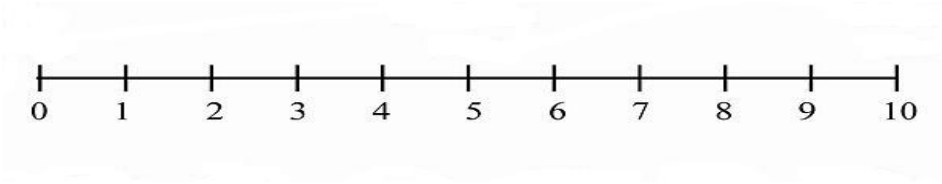
The patients were selected on the basis of the following clinical findings

- Pain and restricted movements of the neck
- Radiating pain in the upper limbs
- Feeling of heaviness in the body and weakness of the limb
- Burning sensation of eyes
- Constipation
- Mental depression
- Tingling sensation and numbness in the upper limbs
- Giddiness and head ache

The history details were taken from the patient about:

- Occupation.
- Social economic status.
- Psychological condition.

UNIVERSAL PAIN SCALE ASSESSMENT:



A. 0 : No Pain

B. 1 -3 : Mild pain

C. 4-6 : Moderate pain

D. 7-10 : Severe pain

Reference: Clinical Manual for Nursing Practice. (National Institute of Health Warren Grant Magnuson Clinical Center)

GRADATION OF MOVEMENTS:

Grade 1	**:**	Fit for all activities to do their work without support (Normal).
Grade 2	**:**	Mild Pain and Mild restriction of Movements.
Grade 3	**:**	Moderate Pain with or without radiation to lower limbs and Moderate restriction of Movements.
Grade 4	**:**	Severe Pain with or without radiation to lower limbs and Severe restriction of Movements.

Diagnosis:

The diagnosis was made by following Siddha diagnosis methods Nilam,Kaalam,Pulanal arithal Poriyal arithal vinaathal Mukkutra Nilaigal Udal Thathukal Nilai and Envagai thervugal,and the diagnosis of cegana vatham were obtained which correlated with diagnosis of cervical Spondylosis by the X-Ray findings.

EXCLUSION CRITERIA:

- Cervical rib
- Trauma
- Spina bifida
- Liver Disease
- Pregnancy and lactation
- Ankylosing spondylosis

- Renal Disease
- Congenital anomalies of spine
- Patient with any other systemic illness
- Recent Dislocation/ trauma

Investigation:

The following investigations were done in all selected patients in the laboratory of Government Siddha Medical College, Palayamkottai.

LABORATORY INVESTIGATIONS:

Blood:

- TC
- DC
- ESR
- Hb
- Blood Sugar
  - Fasting
  - Random
  - Post prandial
- Blood urea
- Serum Creatinine
- Serum Cholesterol
- C-RP

Urine:

- ✓ Albumin
- ✓ Sugar
- ✓ Deposits

SPECIFIC INVESTIGATIONS:

RADIOLOGICAL INVESTIGATION:

- ✓ X- Ray: Cervical spine AP view and lateral view.

TREATMENT

On the first day of treatment 15 ml of Vellai ennai was given at morning with hot water was given.

All the patients were treated with the following medicines.

1.Milagu legiyam

6 grms twice a day

2.Seeraga thylum:

As External application

Varmam was given as a complementary therapy for 15 Ip patients . All the patients were advised to follow dietary regimen (or) pathiyam. The Bio-Chemical analysis was done in the Biochemistry Department and Pharmacological analysis was done in the Pharmacological laboratory of KMCH college of Pharmacy.

RESULTS AND OBSERVATION

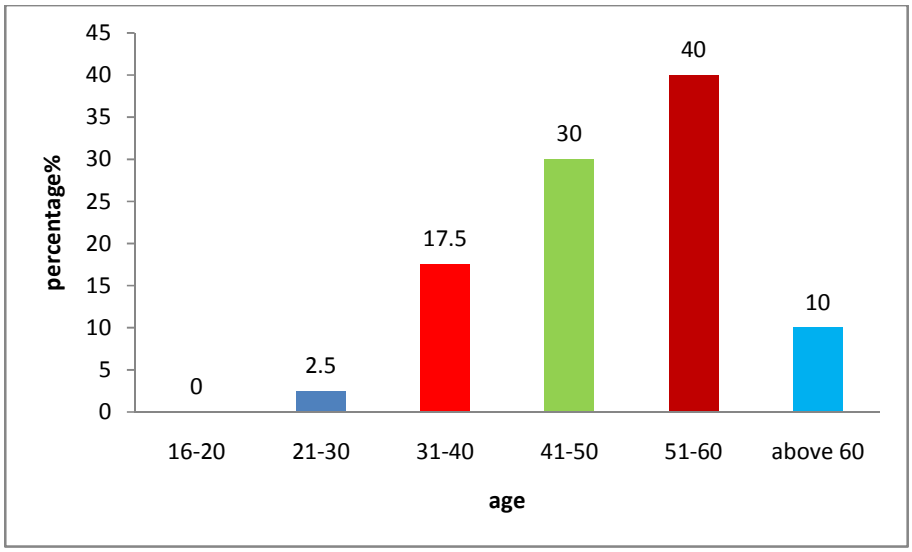
For the clinical study 40 patients were selected and treated in PG-III Sirappu Maruthuvam Department, Government Siddha Medical College and Hospital, Palayamkottai. Results were observed with respect to the following criteria.

1. Age distribution
2. Sex distribution
3. Kaalam
4. Thinai
5. Paruva kaalam
6. Etiological Factors
7. Socio-economic status
8. Occupation
9. Clinical Manifestations
10. Duration of illness
11. Disturbance in vadha
12. Disturbance in pitha
13. Disturbance in kabha
14. Udal Thathukkal
15. Envagai Thervugal
16. Pulse reading (Naadi)
17. Neikuri
18. Provocative test
19. Progress chart
20. Patients treated only with trial drugs
21. Trial drugs along with complementary therapy (Varmam)
22. Effect of Trial drugs along with complementary therapy.
23. Comparison between effective of trial drug and trial drug with complementary therapies
24. Effect of therapy

1. AGE DISTRIBUTION

Out of 40 patients, 40% were 51 – 60 age group and second most 30% were 41 – 50 age group.

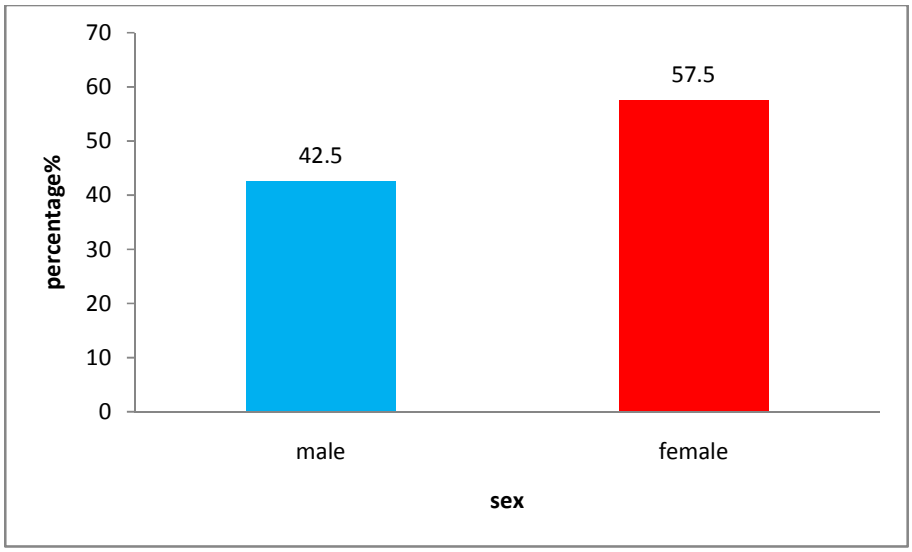
S.no	Age	No. of patients	Percentage(%)
1	16 – 20	-	-
2	21 – 30	1	2.5
3	31 – 40	7	17.5
4	41 – 50	12	30
5	51 - 60	16	40
6	Above 60	4	10



2. SEX DISTRIBUTION

Out of 40 patients, 42.5% were males and 57.5% were females.

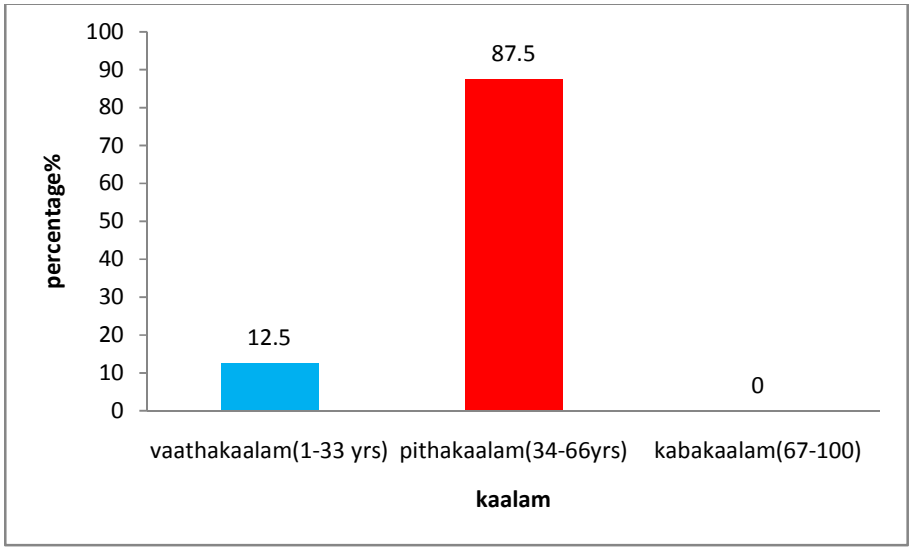
S.no	Sex	No. of cases		Percentage
		Op	Ip	
	Male	9	8	42.5
	Female	16	7	57.5
	Total	25	15	100



3.KAALAM

Out of 40 patients, 12.5% of cases were in the vadha kaalam, 87.5% of cases were in the pitha kaalam, 0 % of cases were in the kabha kaalam

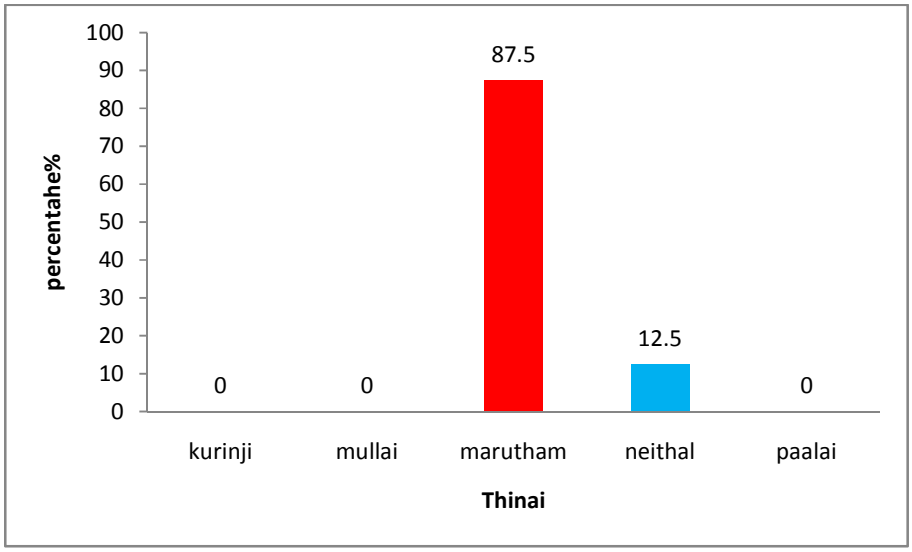
S.no	kaalam	No. of patients	Percentage(%)
1	Vatha kaalam (1-33yrs)	5	12.5
2	Pitha kaalam (34-66yrs)	35	87.5
3	Kaba kaalam (67-100yrs)	-	-



4. THINAI (THE HABITAT OF THE PATIENTS)

Among the 40 patients 87.5% were from marutham and 12.5 % cases were from Neithal thinai.

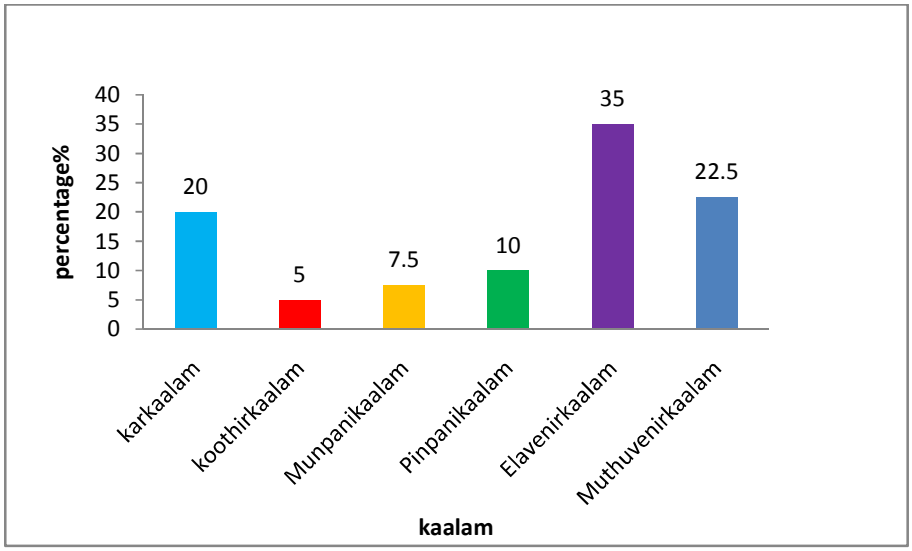
S.no	Thinai or Land	No. of patients	Percentage(%)
1	Kurinji	-	-
2	Mullai	-	-
3	Marutham	35	87.5
4	Neithal	5	12.5
5	paalai	-	-
6	Total	-	-



5. PARUVAKALAM

Among 40 cases, 7.5% of patients were affected in Munpani kaalam 10% of patients were affected in pinpani kaalam and 35% patients were affected in Elavenil kaalam and 5% of patients were affected in Koothir kaalam 22.5% were affected in mudhuvenirkaalam patients. 20% were affected in kaarkalam patients.

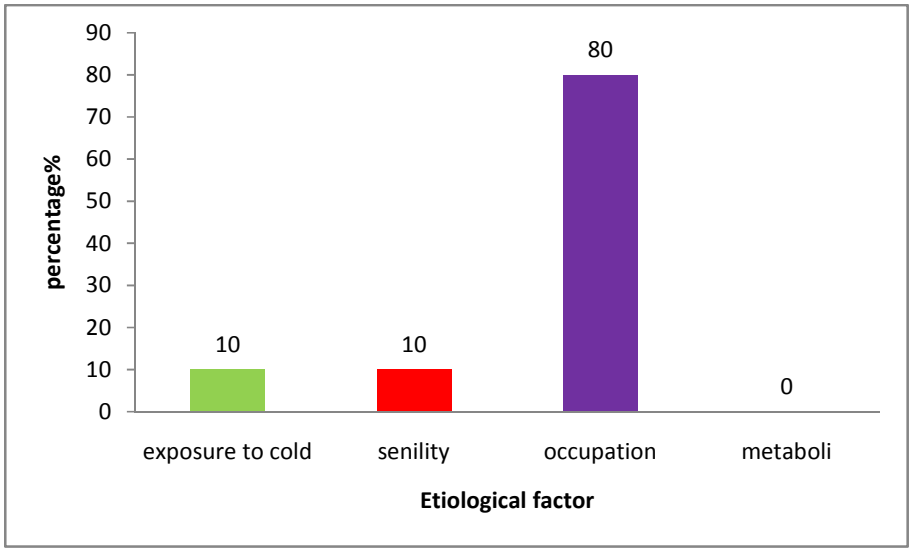
S.no	Paruvakalam	Month	No. of patients	Percentage(%)
1	Kaarkalam	Avani-puratasi (16 aug – 15 oct)	8	20
2	Koothirkaalam	Ippasi-karthigai (16 oct – 15 dec)	2	5
3	Munpanikaalam	Margazhi-thai (16 dec – 15 feb)	3	7.5
4	Pinpanikaalam	Maasi-panguni (16 feb – 15 apr)	4	10
5	Elaveenirkaalam	Chitthirai-vaigasi (16 apr – 15 jun)	14	35
6	muthuvenirkaalam	Aani-aadi (16 jun– 15 aug)	9	22.5



6. DISTRIBUTION BASED ON ETIOLOGICAL FACTORS

It was noted while taking the history of the patients that Ceganavatham was caused mainly (80%) due to the nature of the occupation. The remaining was due to other factor like senility and exposure to cold.

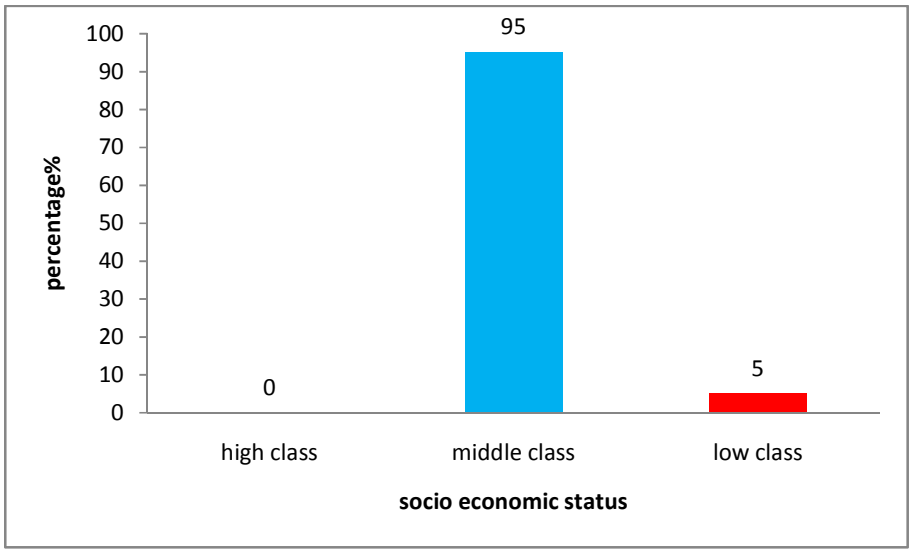
S.no	Precipitating factors	No. of patients	Percentage(%)
1	Exposure to cold	4	10
2	Senility	4	10
3	Occupation	32	80
4	Metabolic	-	-
5	total	40	100



7. SOCIO - ECONOMICAL STATUS

The above study consisted of 0% of cases from rich class, 95% of cases from middle class and 5% of low class

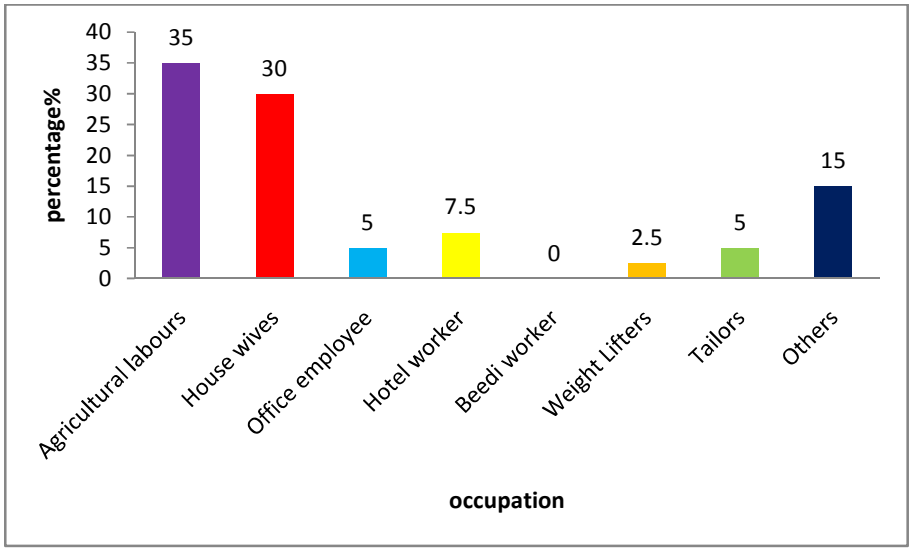
S.no	Socio - Economical status	No. of patients	Percentage(%)
1	Low class	2	5
2	Middle class	38	95
3	High class	-	-
4	Total	40	100



8. OCCUPATION

Out of 40 cases, in this study the rate of incidence is higher in agricultural labour (35%) , hotel workers (7.5%) , Beediworkers (0%), Tailors(5%), weight lifters (2.5%)

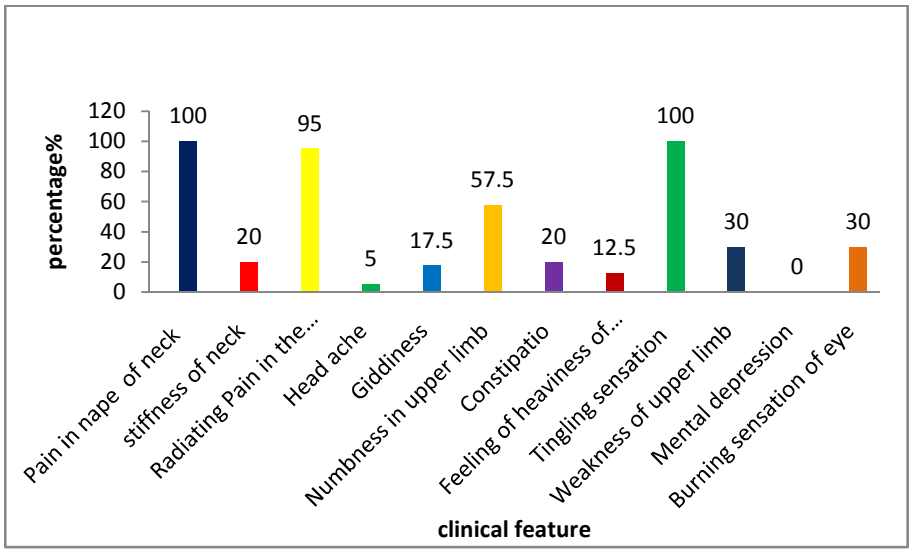
S.no	Occupation	No. of patients	Percentage(%)
1	Agricultural labours	14	35
2	House wives	12	30
3	office employee	2	5
4	Hotel worker	3	7.5
5	Beedi worker	-	-
6	Weight lifters	1	2.5
7	Tailors	2	5
8	Others	6	15



9. CLINICAL MANIFESTATION

Among the 40 cases, all of them had pain in the neck 100% and 20% of patients stiffness in neck, 20% of patients had constipation and 95% of patients had radiating pain in upper limb.

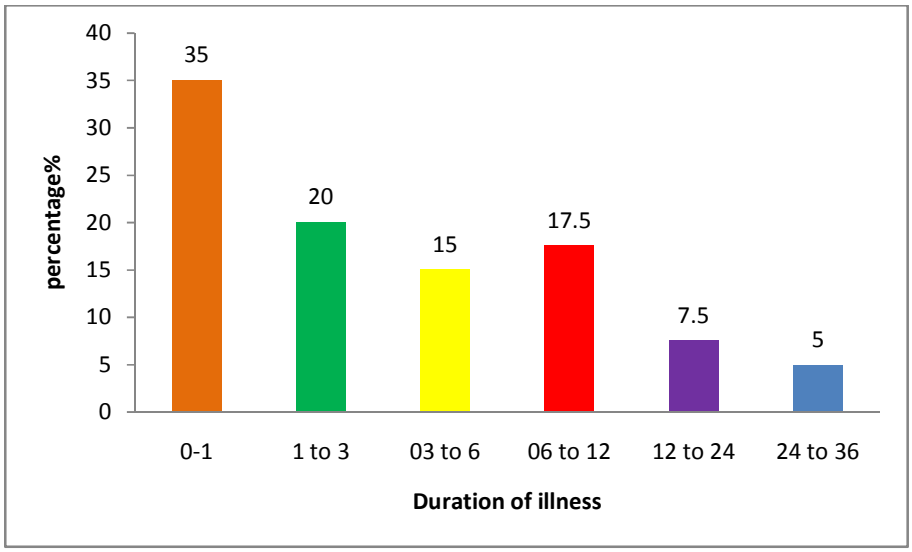
S.no	Clinical features	No. of patients	Percentage(%)
1	Pain in nape of neck	40	100
2	Stiffness in the neck	8	20
3	Radiating pain in the upper limbs	38	95
4	Headache	2	5
5	Diddiness	7	17.5
6	Numbness in upper limb	23	57.5
7	Constipation	8	20
8	Feeling of heaviness of the body	5	12.5
9	Tingling sensation	13	32.5
10	Burning sensation of the eyes	12	30
11	Weakness of the upper limbs	-	-
12	Mental depression	-	-



10. DISTRIBUTION ACCORDING TO THE DURATION OF ILLNESS

From the present study it was studied that the disease Cegana vatham reflected its symptoms mostly over a period of 0-1 months which was confirmed during the history taking while 35% of the patients reported the data

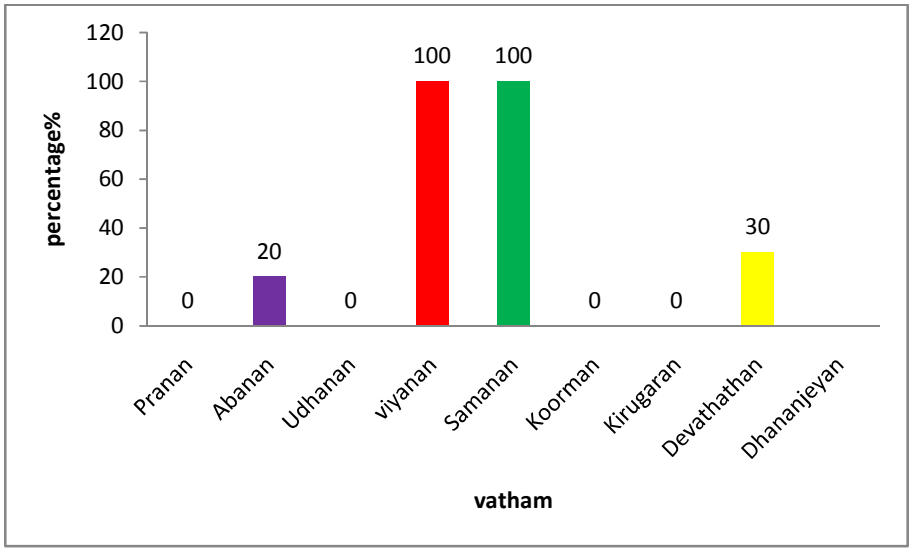
S.no	Duration of illness (in months)	No. of patients	Percentage(%)
1	0 - 1	14	35
2	1 - 3	8	20
3	3 - 6	6	15
4	6 - 12	7	17.5
5	12 - 24	3	7.5
6	24 - 36	2	5



11. DISTURBANCE IN VATHAM

Among the 10 types of vatha, Samanan and viyanan were affected in all the cases (100%). Abanan was noted to be deranged in 20% and Devathathan was abnormal in 30%.

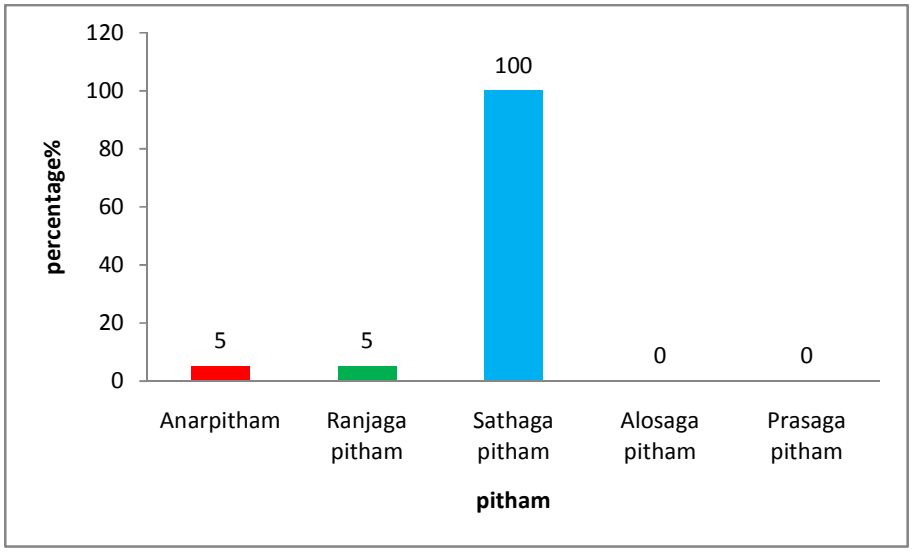
S.no	Vatham	No. of patients	Percentage(%)
1	Piranan	-	-
2	Abanan	8	20
3	Vudhanan	-	-
4	Viyanan	40	100
5	Samanan	40	100
6	Naagan	-	-
7	Koorman	-	-
8	Kirukaran	-	-
9	Devathathan	12	30
10	Thananjayan	-	-



12. DISTURBANCES IN PITHAM

The five types of pitham were analyzed in all 40 cases, Sathaga pitham was altered in all cases (100%) evidenced as difficulty in handling their regular duties because of pain and stiffness in neck and upper limb. Ranjaga pitham was affected in 5% patients denoting low haemoglobin count.

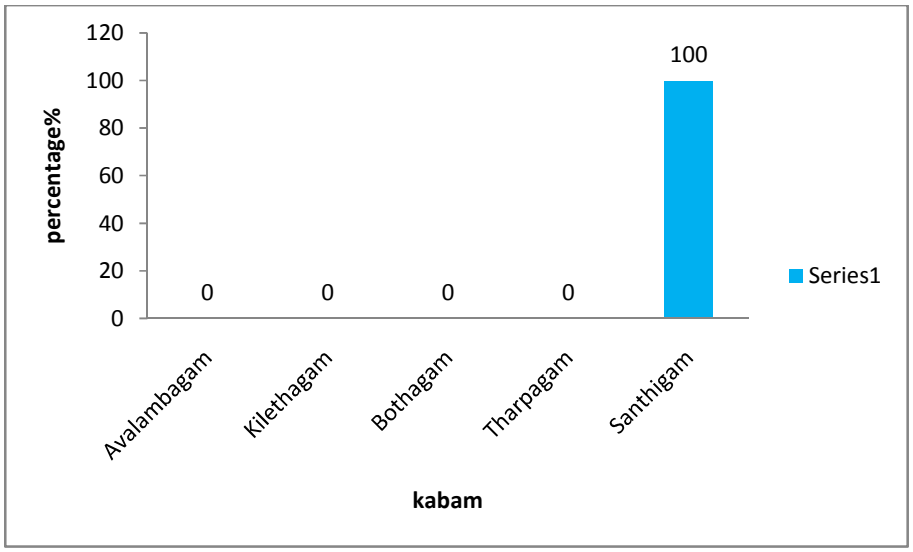
S.no	Pitham	No. of patients	Percentage(%)
1	Anarpitham	2	5
2	Ranjagapitham	2	5
3	Sathagapitham	40	100
4	Aalosagapitham	-	-
5	pirasagapitham	-	-



13. DISTURBANCES IN KABAM

Santhigam was observed to be affected in all the cases.

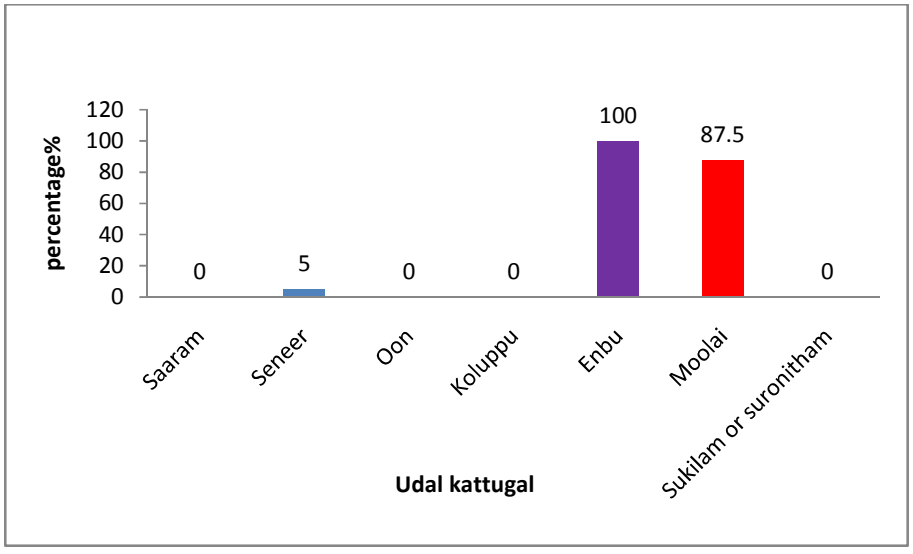
S.no	kabam	No. of patients	Percentage(%)
1	Avalambagam	-	-
2	Kilethagam	-	-
3	Pothagam	-	-
4	Tharpagam	-	-
5	Santhigam	40	100



14. INVOLVEMENT OF UDAL KATTUKAL

It was diagnosed during the study Enbu 100%, Moolai 87.5% cases were affected.

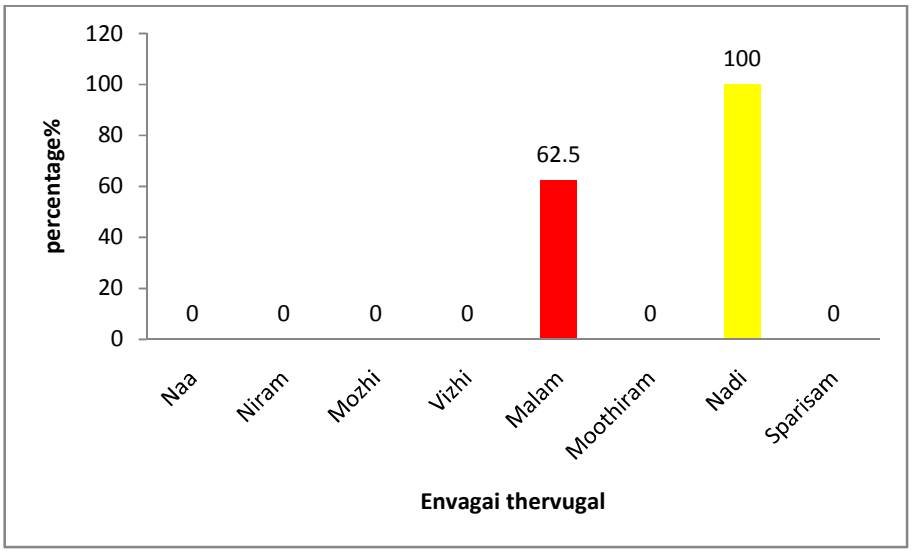
S.no	Udal kattukal	No. of patients	Percentage(%)
1	saaram	-	-
2	senneer	2	5
3	oon	-	-
4	kozhuppu	-	-
5	enbu	40	100
6	Moolai	35	87.5
7	Sukkilam / suronitham	-	-



15. CONDITION OF ENVAGAI THERVUGAL

It was learnt during the study that thontha naadi was noted in all 40 cases, malam was affected in 62.5% of cases

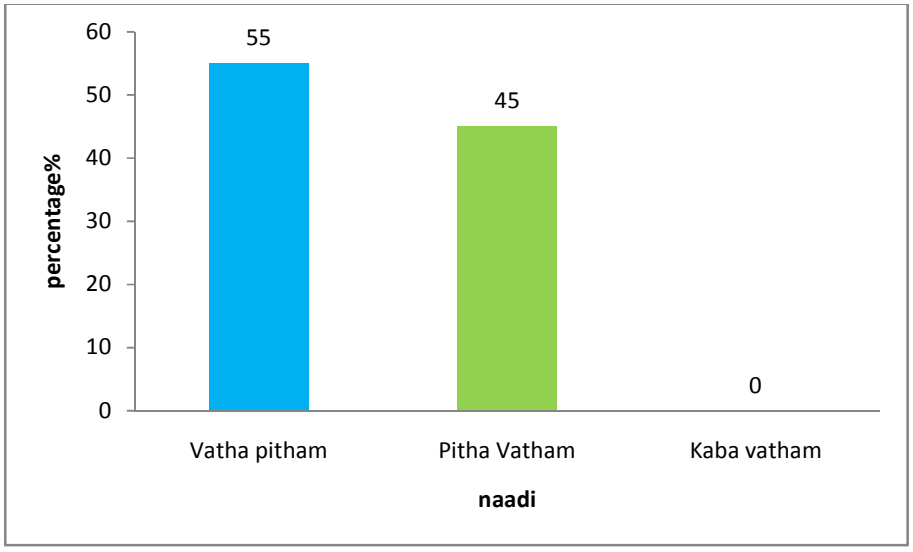
S.no	Envagai thervugal	No. of patients	Percentage(%)
1	Naa	-	-
2	Niram	-	-
3	Mozhi	-	-
4	Vizhi	-	-
5	Malam	25	62.5
6	Moothiram	-	-
7	Naadi(thontha naadi)	40	100
8	Sparisam	-	-



16. NAADI

As mentioned above thontha naadi was noted in all cases and among them 55% were vatha pitha naadi 45% were pitha vatha naadi

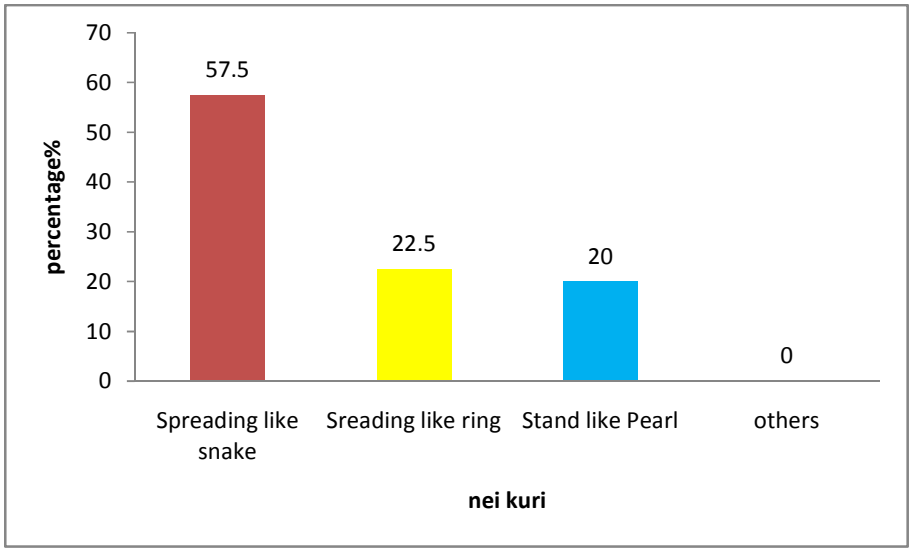
S.no	parameters	No. of patients	Percentage(%)
1	Vatha pitham	22	55
2	Pitha vatham	18	45
3	Kaba vatham	-	-



17 NEIKURI

In neikuri analysis 57.5% of the cases presented with vatha neer, 22.5% with pitha neer, 20% with kaba neer

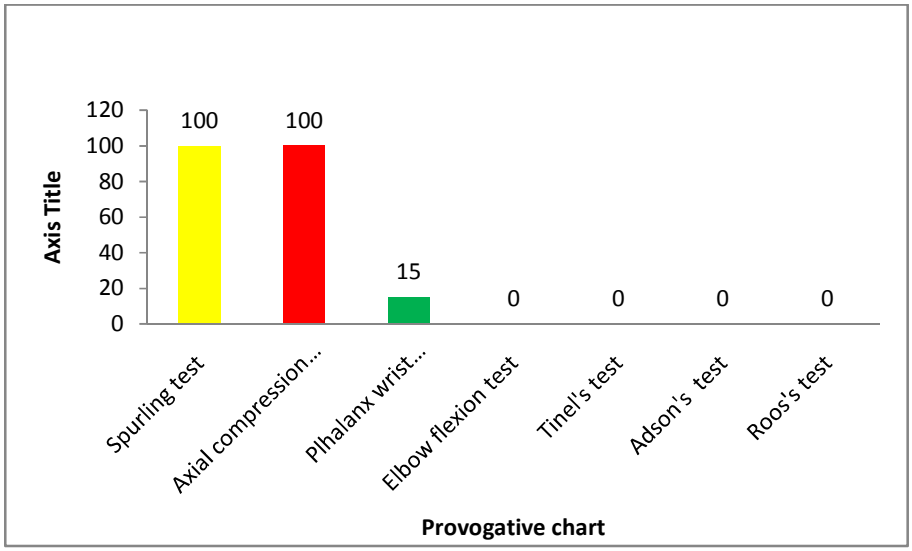
S.no	Inference	No. of patients	Percentage(%)
1	Spreading like snake	23	57.5
2	Spreading like ring	9	22.5
3	Stants like a pearl	8	20
4	Others	-	-
5	Total	40	100



18. PROVOCATIVE TESTS

Based on modern aspect, for the diagnostic purpose and to determine the differential diagnosis few provocative tests were done and noted in all 40 cases spurling test, axial compression sign were positive in all cases (100%) and tinel's sign, adson's test. Roo's test were negative in all cases.

S.no	Test	No. of patients	Percentage
1	Spurling test	40	100
2	Axial compression test	40	100
3	Phalanx wrist flexion tet	6	15
4	Elbow flexion test	0	0
5	Finger escape sign	0	0
6	Tinels sign	0	0
7	Adson test	0	0
8	Roos test	0	0



19. PROGRESSIVE CHART

It was noted that, clinical manifestations like pain in the neck, restriction of movements and radiation of pain to other parts were remarkably reduced after treatment when compared to that of before treatment, Numbness and tenderness showed moderate reduction after treatment.

S.no	Clinical feature	Before treatment		After treatment	
		No.of cases	Percentage	No.of cases	percentage
1	Pain in neck	40	100	1	2.5
2	Pain in shoulder	38	95	2	5
3	Radiating pain in the right upper limb	22	55	2	5
4	Radiating pain in the left upper limb	16	40	-	-
5	Numbness	23	57.5	-	-
6	Tenderness	-	-	-	-
7	Restriction of movement(ROM)	5	12.5	-	-
8	Burning sensation	12	30	-	-
9	Giddiness	7	17.5	-	-

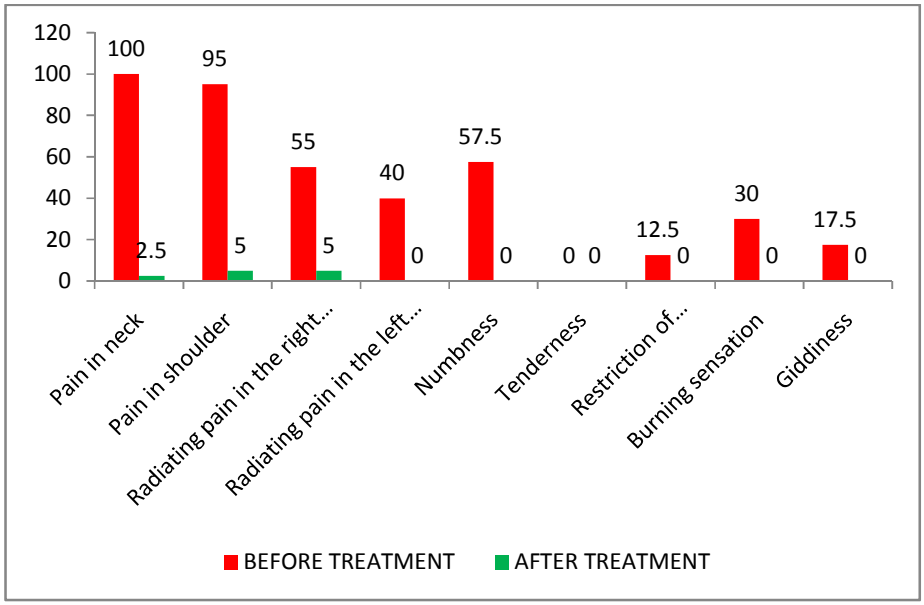


Table 20. Assessment of curative effects in patients treated only with trail drug (internal and external medicines)

From the above study, it was inferred that severe pain that was noted in patients before treatment (47.5%) had a remarkable decline after treatment (5%), similarly moderate and mild pain (7.5%) were also observed to have decreased after treatment

symptoms	Initial readings		Final readings	
	No of patients	percentage	No of patients	Percentage
No pain	-	-	19	47.5
Mild	9	22.5	3	7.5
Moderate	12	30	2	5
severe	4	10	1	2,5

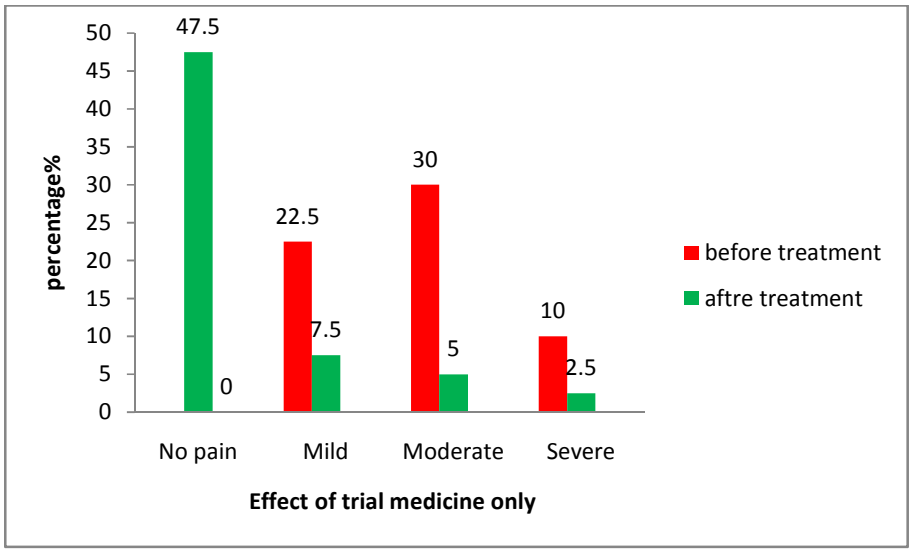


Table 21. Assessment of curative effects in cervical spondylosis patients treated with trail drugs along with complimentary therapy (Varmam)

Administration of trial drug along with complementary therapy reduced severe pain in almost all the cases pain reduced in mild and moderate cases.

symptoms	Initial readings		Final readings	
	No of patients	percentage	No of patients	Percentage
No pain	-	15	12	30
Mild	6	17.5	2	5
Moderate	7	5	1	2.5
severe	2		-	

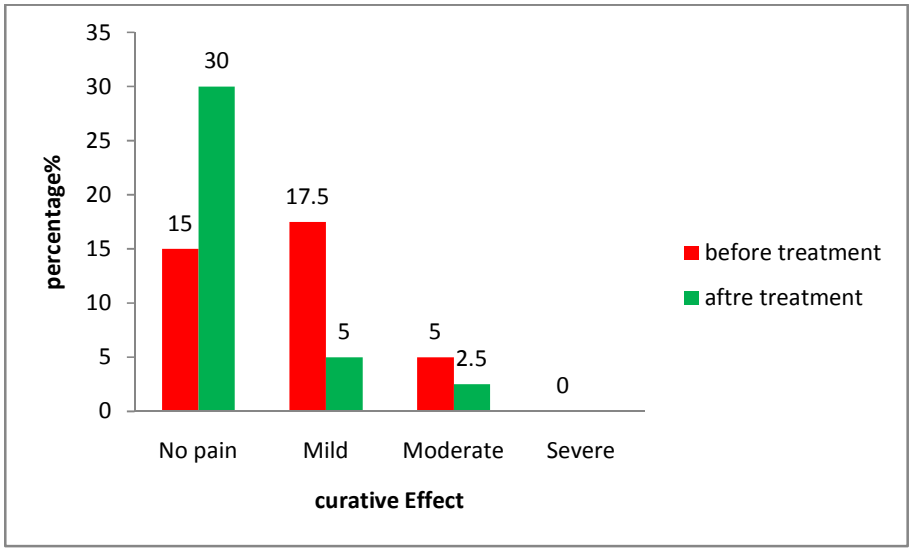


Table 23. Effect of trail drug along with complementary therapies

Administration of trial drug along with complementary therapies had a marked response 77.5% moderate with 7.5% and mild with 12.5%

S.no	Effect of therapy	No. of patients	Percentage(%)
1	Marked effect	31	77.5
2	Moderate effect	3	7.5
3	Mild effect	5	12.5
4	No effect	1	2.5

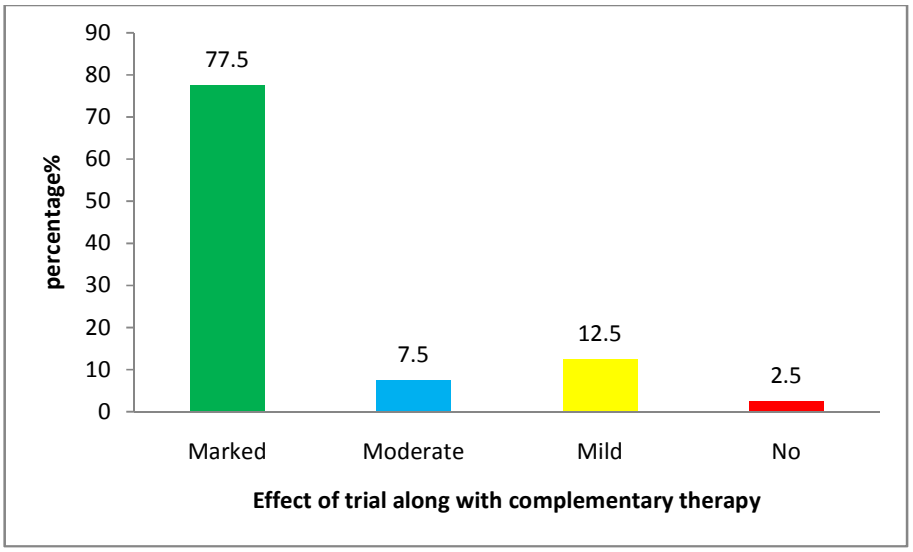
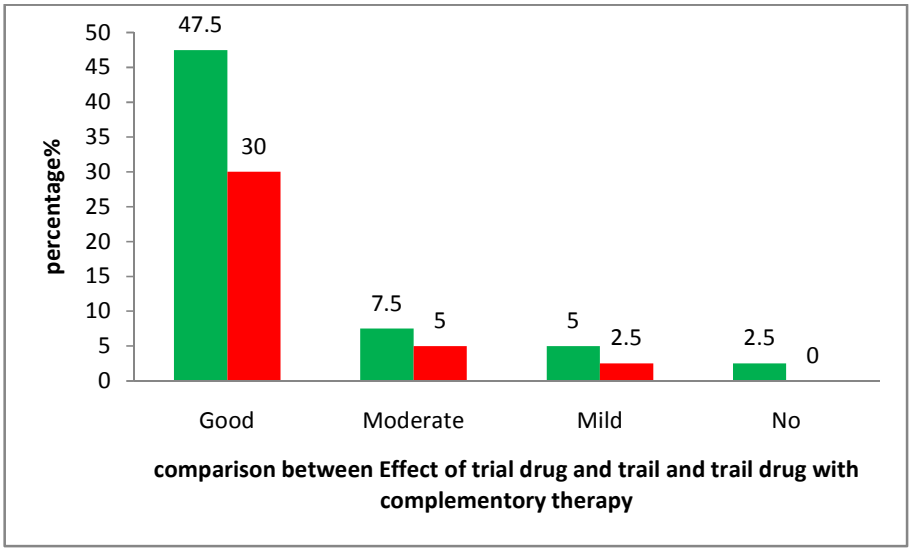


Table 24. Comparison between effective of trail drug and trail drug with complementary therapies

From the above data, it can be concluded that administration of trial drug along with complementary therapies had comparatively more effect than administering trial drug alone.

S.no	Effect of therapy	Trail drug alone		Trail drug with external therapy	
		No.of cases	percentage	No.of cases	percentage
1	Good	19	47.5	12	30
2	Moderate	3	7.5	2	5
3	Mild	2	5	1	2.5
4	No	1	2.5	-	-



LIST OF OUT PATIENTS OF PG III SIRAPPU MARUTHUVAM DEPARTMENT GIVEN

1.MILAGU LEGIYAM – INTERNAL 2.SEERAGA THYLAM – EXTERNAL

S.no	Op.no	Name	Age/sex	Occupation	Date of admission	Date of discharge	Total no. of days treated	Results
1	62553	Parvathy	33/F	House wife	22.07.17	07.09.17	48days	Good
2	107393	Mareeswari	45/F	House wife	5.12.17	21.01.18	48 days	Mild
3	109483	Noorjahan	57/F	House wife	11.12.17	27.01.18	48 days	Good
4	11994	Musthafa	58/F	Weight lifter	15.12.17	31.01.18	48 days	Good
5	1000	Sankaran	40/F	Former	03.01.18	13.02.18	42 days	Good
6	1509	Papathy	45/F	Former	04.01.18.	17.02.18	45 days	Good
7	1510	Parvathy	33/F	House wife	04.01.18	20.02.18	48 days	Good
8	21946	Mariyammal	51/F	House wife	05.01.18	19.02.18	47 days	Good
9	2682	Selvarai	60/F	Former	06.01.18	22.02.18	48 days	Moderate
10	3748	Balasubramaniyan	55/F	Former	09.01.18	14.02.18	37 days	Mild
11	5690	Rahumath	52/F	Clerk	17.01.18	28.02.18	43 days	Good
12	2834	Sivakumar	35/F	Former	07.02.18	26.03.18	48 days	Good
13	13314	Chokalingam	51/F	Former	08.02.18	20.03.18	41 days	Good
14	14911	Saraswathy	47/F	Clerk	13.02.18	30.03.18	46 days	Good
15	15103	Parvatham	49/F	Former	15.02.18	31.03.18	45 days	Moderate
16	16008	Thasmi	47/F	Tailor	15.02.18	03.04.18	48 days	Good
17	16475	Ramachandiran	62/F	Former	17.02.18	05.04.18	48 days	Mild
18	16735	Saraswathi	45/F	Former	17.02.18	02.04.18	45 days	Good
19	18255	Chithambaram	54/F	Former	22.02.18	02.04.18	40 days	Good
20	19068	Balasubramaniyan	50/F	Photographer	24.02.18	09.04.18	45 days	Good
21	20687	Ruthra	23/F	Backery worker	01.03.18	17.04.18	48 days	Good
22	27047	Seyathoon	31/F	Tailor	21.03.18	30.04.18	41 days	Good
23	24475	Jayarani	50/F	Teacher	15.03.18	30.04.18	47 days	Good
24	28486	Meena	38/F	Shop keeper	25.03.18	09.05.18	46 days	Good
25	32624	Alagammal	45/F	Teacher	08.04.18	25.05.18	48 days	Good

LIST OF IN PATIENTS OF PG III SIRAPPU MARUTHUVAM DEPARTMENT GIVEN

1.MILAGU LEGIYAM – INTERNAL 2.SEERAGA THYLAM – EXTERNAL

S.no	Ip.no	Name	Age/sex	Occupation	Date of admission	Date of discharge	Total no. of days treated	Results
1	3196	Selvarani	45/F	House wife	06.12.17	29.12.17	24 days	Good
2	3206	Krishnaveni	42/F	House wife	07.12.17	26.12.17	20 days	Good
3	3327	Somu	60/M	Hotel worker	10.12.17	25.01.18	47 days	Good
4	3346	Alagusundari	56/F	House wife	26.12.18	18.01.17	24 days	Moderate
5	72	Masilamani	60/M	Former	17.01.18	05.02.18	20 days	Good
6	147	Revathy	32/F	House wife	22.01.18	25.02.18	35 days	Good
7	153	Latchmanasamy	52/M	former	23.01.18	28.02.18	37 days	Good
8	491	Murugan	50/M	Hotel worker	22.02.18	13.03.18	20 days	No improvement
9	627	Manuvel	53/M	Former	08.03.18	26.03.18	19 days	Moderate
10	672	Palraj	54/M	Hotel worker	12.03.18	28.03.18	17 days	Good
11	677	Chinnathai	62/F	House wife	13.03.18	02.04.18	21 days	Good
12	696	Manikavel	60/M	Former	14.03.18	02.04.18	20 days	Good
13	746	Thiruveni	63/F	House wife	19.03.18	21.04.18	34 days	Good
14	1141	Sornam	58/F	House wife	26.04.18	07.06.18	43 days	Moderate
15	1144	selvaraj	65/M	watchman	27.04.18	07.06.18	42 days	Good

BLOOD INVESTICATION BEFORE AND AFTER TREATMENT – OP PATIENT

S.N	OP.NO	TC		DC										HB		ESR		BLOOD SUGAR				BLOOD UREA		SERUM CHOLESTEROL	
				N		L		E		B		M						F		PP					
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	62553	8200	8100	76	78	20	22	4	-	0	0	0	0	11.5	12	15	12	90	80	120	125	27	25	165	169
2	107393	7600	7800	68	70	29	28	3	2	0	0	0	0	9.7	11.5	18	13	84	85	111	120	32	31	167	171
3	109483	7400	7600	73	73	23	25	4	2	0	0	0	0	12.6	12.6	7	14	83	90	121	128	25	27	207	201
4	11994	8000	8200	65	68	33	30	2	2	0	0	0	0	11.7	12.1	14	11	88	85	130	120	31	29	115	125
5	1000	7800	8000	78	78	21	22	1	-	0	0	0	0	10.9	12	20	24	96	80	120	130	29	32	170	157
6	1509	8000	7800	69	69	30	29	1	2	0	0	0	0	11.8	10.9	22	17	82	82	112	120	38	35	155	159
7	1510	6800	6600	72	73	23	24	5	3	0	0	0	0	12.8	12.7	18	19	80	83	124	126	33	31	163	161
8	21946	7200	7200	60	61	38	39	2	1	0	0	0	0	12	11.8	20	18	86	82	118	120	25	23	157	153
9	2682	7300	7900	67	67	28	30	5	3	0	0	0	0	12.2	12.8	17	15	89	88	120	111	23	27	147	151
10	3748	7500	7600	76	77	22	23	2	-	0	0	0	0	10.2	10.6	18	16	88	86	118	100	24	23	143	147
11	5690	7800	7600	57	59	36	36	7	5	0	0	0	0	9.8	9.9	15	19	79	83	120	125	28	30	151	153
12	2834	8000	8000	73	75	25	25	2	-	0	0	0	0	11.6	12.5	21	18	83	85	115	120	33	31	148	151
13	13314	8200	8100	72	72	27	26	1	2	0	0	0	0	12.7	12.7	24	20	79	83	118		36	33	157	159
14	14911	8400	7200	65	67	31	32	4	1	0	0	0	0	11.8	10.9	14	7	86	77	130	128	31	29	155	155
15	15103	7600	7400	61	63	37	37	2	-	0	0	0	0	12.5	12.3	13	18	79	83	118	120	34	35	129	131
16	16008	7500	7600	67	69	38	38	5	3	0	0	0	0	11	12.5	12	15	88	70	120	112	29	31	199	197
17	16475	6800	8000	69	71	28	28	3	1	0	0	0	0	10	11.5	24	22	80	86	130	110	26	30	187	181
18	16735	7400	7800	62	63	35	36	3	1	0	0	0	0	9.8	12.0	18	17	83	90	125	115	22	27	181	179
19	18255	7800	8000	68	66	27	29	5	5	0	0	0	0	11.8	12.5	20	18	95	100	110	120	36	31	179	174
20	19068	6800	7200	67	69	30	31	3	-	0	0	0	0	10.5	11.6	18	17	86	84	123	118	25	23	171	169
21	20687	7200	7400	67	69	28	30	5	1	0	0	0	0	10.5	12.3	21	19	94	90	113	120	38	37	167	165
22	27047	7300	7600	73	73	26	25	1	2	0	0	0	0	12.6	12.8	18	15	88	81	125	110	33	28	169	171
23	24475	7600	7800	77	75	23	24	-	1	0	0	0	0	11.7	11.8	21	17	81	88	123	110	21	20	159	160
24	28486	7800	8200	71	73	26	26	3	1	0	0	0	0	10.6	11	18	16	90	85	110	120	27	27	161	162
25	32624	8600	8800	72	72	28	25	-	1	0	0	0	0	12.0	12.3	17	15	85	93	118	130	31	30	205	201

BLOOD INVESTICATION BEFORE AND AFTER TREATMENT – IP PATIENT

S.NO	OP.NO	TC		DC										HB		ESR		BLOOD SUGAR				BLOOD UREA		SERUM CHOLESTEROL	
				N		L		E		B		M						F		PP					
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1.	3196	8500	9100	66	65	29	31	5	4	0	0	0	0					80	83	120	125	15	18	150	153
2.	3206	8500	8400	68	67	32	32	-	1	0	0	0	0	8.9	9.2	15	17	90	95	116	121	18	21	155	167
3.	3327	8200	8500	54	61	43	36	3	3	0	0	0	0	9.2	10.5	9	11	96	99	135	132	35	33	190	189
4.	3346	8400	8700	59	67	41	29	-	4	0	0	0	0	12.2	13	21	19	86	85	110	117	16	19	126	131
5.	72	6900	6900	66	65	29	31	5	4	0	0	0	0	11.6	12.5	12	10	92	92	116	119	13	17	215	205
6.	147	7300	7200	64	62	32	36	4	2	0	0	0	0	13.1	13	14	13	88	87	108	113	11	15	175	179
7.	153	9100	9400	76	71	20	28	4	1	0	0	0	0	9.5	10.7	9	11	92	93	125	127	25	29	166	169
8.	491	6900	7100	64	63	29	31	7	6	0	0	0	0	12.1	11.6	8	9	95	94	128	131	27	31	150	159
9.	627	8100	8700	64	69	25	26	9	5	0	0	0	0	12.8	12.2	6	7	84	86	130	139	16	19	175	177
10.	672	7200	7100	71	70	27	28	2	2	0	0	0	0	11	11.5	23	21	89	92	116	123	26	27	147	151
11.	677	6400	6300	76	69	20	28	4	3	0	0	0	0	10.5	12.9	27	25	81	87	120	127	14	18	245	235
12.	696	7000	7300	60	62	34	34	6	4	0	0	0	0	12	12.2	17	18	99	98	132	135	18	21	135	191
13.	746	9000	9100	57	59	36	37	7	4	0	0	0	0	11.1	11.9	19	20	90	93	111	127	12	13	397	390
14.	1141	8200	8400	62	60	34	35	4	5	0	0	0	0	12.4	13.1	23	21	73	81	114	135	26	24	185	189
15.	1144	7300	7200	64	66	33	31	3	3	0	0	0	0	9.5	10.8	11	8	92	93	129	138	22	20	220	221

URINE EXAMINATION BEFORE & AFTER TREATMENT – OP PATIENTS

S.no	OP.no	Before treatment			After treatment		
		Albumin	Sugar	Deposit	Albumin	Sugar	Deposit
1	62553	Nil	Nil	NAD	Nil	Nil	NAD
2	107393	Nil	Nil	NAD	Nil	Nil	NAD
3	109483	Nil	Nil	NAD	Nil	Nil	NAD
4	11994	Trace	1-2 Puscells	NAD	Nil	Nil	NAD
5	1000	Nil	Nil	NAD	Nil	Nil	NAD
6	1509	Nil	Nil	NAD	Nil	Nil	NAD
7	1510	Nil	Nil	NAD	Nil	Nil	NAD
8	21946	Nil	Nil	NAD	Nil	Nil	NAD
9	2682	Nil	Nil	NAD	Nil	Nil	NAD
10	3748	Nil	Nil	NAD	Nil	Nil	NAD
11	5690	Nil	Nil	NAD	Nil	Nil	NAD
12	12834	Nil	Nil	NAD	Nil	Nil	NAD
13	13314	Nil	Nil	NAD	Nil	Nil	NAD
14	14911	Nil	Nil	NAD	Nil	Nil	NAD
15	15103	Nil	Nil	NAD	Nil	Nil	NAD
16	16008	Nil	Nil	NAD	Nil	Nil	NAD
17	16475	Nil	Nil	NAD	Nil	Nil	NAD
18	16735	Nil	Nil	NAD	Nil	Nil	NAD
19	18255	Nil	Nil	NAD	Nil	Nil	NAD
20	19068	Nil	Nil	NAD	Nil	Nil	NAD
21	20687	Nil	Nil	NAD	Nil	Nil	NAD
22	27047	Nil	Nil	NAD	Nil	Nil	NAD
23	24975	Nil	Nil	NAD	Nil	Nil	NAD
24	28486	Nil	Nil	NAD	Nil	Nil	NAD
25	32624	Nil	Nil	NAD	Nil	Nil	NAD

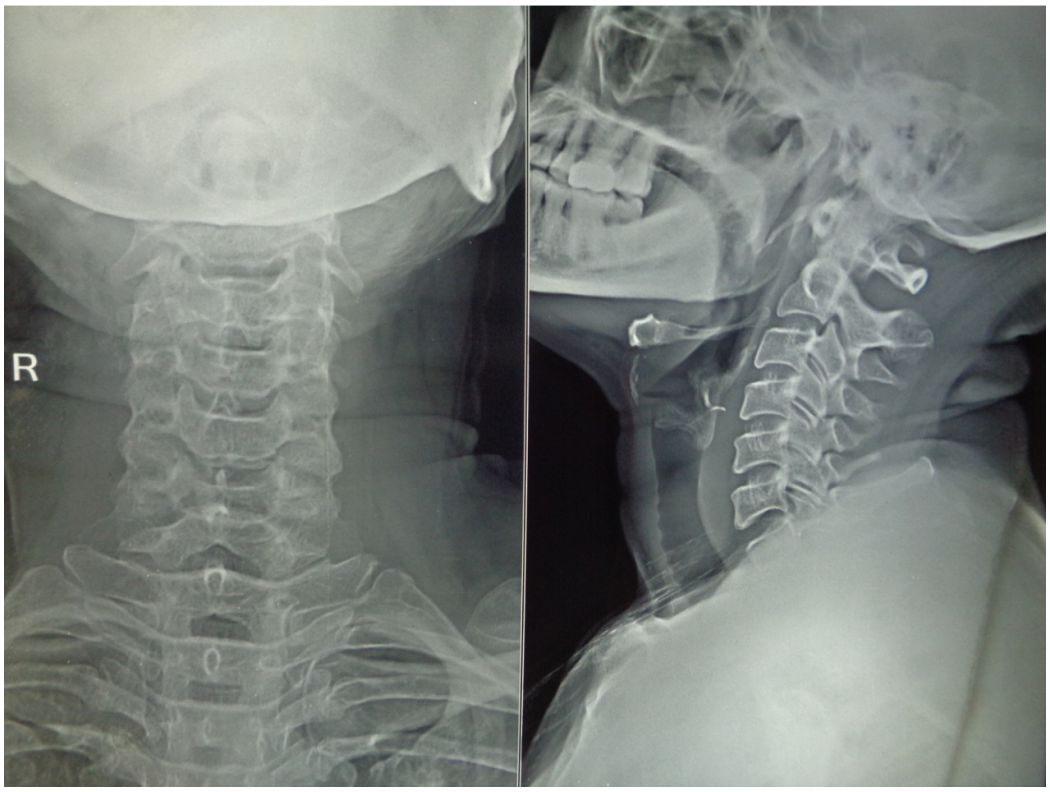
URINE EXAMINATION BEFORE & AFTER TREATMENT – IN PATIENTS

S.no	IP.no	Before treatment			After treatment		
		Albumin	Sugar	Deposit	Albumin	Sugar	Deposit
1	3196	Nil	Nil	NAD	Nil	Nil	NAD
2	3206	Nil	Nil	1-2 Epithelial cells	Nil	Nil	NAD
3	3327	Nil	Nil	NAD	Nil	Nil	NAD
4	3346	Nil	Nil	NAD	Nil	Nil	NAD
5	72	Nil	Nil	NAD	Nil	Nil	NAD
6	147	Nil	Nil	NAD	Nil	Nil	NAD
7	153	Nil	Nil	1-2 Epithelial cells	Nil	Nil	NAD
8	491	Nil	Nil	NAD	Nil	Nil	NAD
9	627	Nil	Nil	NAD	Nil	Nil	NAD
10	672	Nil	Nil	1-2 Epithelial cells	Nil	Nil	NAD
11	677	Nil	Nil	NAD	Nil	Nil	NAD
12	696	Nil	Nil	NAD	Nil	Nil	NAD
13	746	Nil	Nil	NAD	Nil	Nil	NAD
14	1141	Nil	Nil	NAD	Nil	Nil	NAD
15	1144	Nil	Nil	NAD	Nil	Nil	NAD

X- RAY – CERVICAL SPINE PA - LATERAL

OP.NO : 32624

Name : Alagammal 45 / F



DISCUSSION

Based on the clinical manifestations discussed in Yugi vaithiya chinthamani-800. 40 cases were enrolled for the study. Envagaithervugal the siddha diagnostic method was used to diagnose the disease and it was confirmed with the modern investigations. After confirmation of the diagnosis the trial drug was administered along with the special therapies. Observations were noted and analysed. They are discussed here under.

Age distribution

The statistical study shows high incidence of Cegana vatham in the age group between 51-60 years as it is one of the degenerative disease and lowest incidence in the age between 21-30.

Most of the patients belong to pithakalam.

This information is best owed by our siddhars as the wordings.

"வேண்டா ஐம்பதாம் வயதுதன்னில்

விரைந்துபிருதிவியில் அப்புமேவும் பாரே".

The target sites affected in cervical spondylosis are generally bones, muscles, nerves, hairs, blood, urine, fat which are the components of appu and prithiviboothas (Appu+ prithivi = kabam responsible for destruction). Hence they begin to degenerate above fifty.

Sex distribution

There is a slight variation in the male and female ratio and it is noted obviously in the study.

Thinai

About 87.5% of patients from maruthanilam. It may be due to altered food, lifestyle,habits etc.

Seasonal distribution

Most of the patients came during, Elavenil kaalam,Muthuvenil kaalam, Pinpani kaalam, Munpani kaalam, .

Etiological factors

Majority of patients of the Ceganavatham was caused mainly (80%) due to the nature of occupation. The remaining was due to other factor like senility and exposure to cold.

Socio-economic status

During the study, 95% of cases were middle class and 5% of lower class.

Occupational status

The rate of incidence is higher in occupational group which includes Agricultural labour (35%) and house wifes(30%) Hotel workers, Tailors, Weight lifters, others(35%). Due to Agricultural labours are mostly affected.

Clinical Manifestations

Pain in the nape of the neck is present in all 40 cases (100%), 95% of cases had radiating pain in upper limbs 20% of cases had stiffness in the Neck. Hence symptoms associated very well with the disease as proved by the statistical tests.

Duration of illness

Most of the patient with the disease Cegana vatham reflected its symptoms over a period of 0-1 month which was confirmed during the history taking while 35% of the patients reported the data.

Derangement in vatha

Viyanan and Samanan was affected in all 40 cases (100%).Abanan affected in 8 cases 20% Devathathan affected in 12 cases (30%).

Disturbances in Pitha

Mostly Sathagapitham was affected in all 40 cases (100%).

Disturbances in Kabha

Almost Santhigam was affected in all 40 cases (100%).

Udal Thathukkal

Saaram affected in 5% Enbu 100% and Moolai affected in 87.5%.

Envagai Thervugal

In this study thontha naadi was noted in all 40 cases, malam was affected in 62.5% of cases and.

In naadi 55% were vatha pitha naadi, 45% were pitha vatha naadi.

Investigation

Laboratory investigations were done in all the cases before and after treatment. The significant variation occurs in parameters like ESR and HB, while other parameters have insignificant variation.

Pre clinical studies

The Bio chemical analysis of "MILAGU LEGIYAM" contains Calcium, Sulphate, Chloride, Ferrous iron, Unsaturated compound, Reducing sugar, Amino acid.

Pharmacological studies

The pharmacological studies done in MILAGU LEGIYAM revealed the presence of actions such as

1. Anti – inflammatory action
2. Analgesic activity.

Toxicity studies

Acute toxicity and subacute studies in rats for "MILAGU LEGIYAM" revealed that it has no toxicity effect.

Treatment

The treatment was aimed to retain the Deranged thoshas and providing relief from symptoms. Before treatment the patients were advised to take vellai ennai 15ml with hot water during morning for first day of treatment.

From the second day onwards Internal medicine MILAGU LEGIYAM 6gm two times a day after food and Seeraga thylam is given as external.

At the time of treatment the patients were advised to follow pathiyam and specifically advised to avoid foods which increase vadha.

Along with the course of treatment the complementary therapy like Varmam is given additionally to some of the patients.

The outcome of this study is mainly assessed by reduction in pain in cervical region. Increased range of reduction of restricted movements and improvement in quality of life universal pain assessment scale was also used to detect proper outcome. No adverse effect was noted for both internal and external medicine along with the course of treatment.

SUMMARY

40 cases with Cegana vatham were diagnosed clinically based on yugi - 800 and admitted in the Inpatient ward and Outpatient ward of post graduate department of sirappu maruthuvam, Government Siddha Medical College Hospital, palayamkottai and treated by the trial medicines.

- Laboratory diagnosis of Ceganavatham was done by siddha diagnostic principles and endorsed by modern methods of investigations.
- The various siddha aspects of examination of the disease were carried out and were recorded in the proforma.
- The trial medicine chosen for both internal and external treatments were Milagu legiyam – 6gms/days BD doses for forty eight days as per the severity of the diseases,Seeraga thylam (External)
- Before starting the treatment careful detailed history was carried out and recorded for the forty selected cases.
- During the period of treatment all the patients were put under pathiyam (A specific dietary regimen)
- A periodical laboratory investigation was made for all the cases along with the radiological investigations.
- The observations made during the clinical study shows that the main internal drug MILAGU LEGIYAM is clinically effective.
- Though there was appreciable clinical improvement, there were not much remarkable radiographic changes.

  The action of external application Seeraga thylam with Varmam as a Complementory therapy is also quite remarkable.

CONCLUSION

All 40 patients (25 OPD and 15 IP – 25 Cases with trial medicines and Massage, 15 Cases varmam along with trial medicines). Were treated for this dissertation work with Milagu Legiyam 6gm/day in twice a day divided doses and Seeraga thylam (externally)

In the preclinical study pharmacological evaluation of the trial drug shows.

Significant analgesic effect

Significant Anti inflammatory effect (Internal medicine)

In the preclinical study toxicity study of "Milagu Legiyam" shows that the trial drug had no acute toxicity.

The overall effect of the clinical trial drug are

Marked effect	-	77.5 %
Moderate effect	-	12.5 %
Mild effect	-	7.5 %
No effect	-	2.5 %

This result of the clinical trial illustrates the marked effect of the drugs and complementary therapy.

The trial drug Milagu Legiyam and external Seeraga thylam is effective. No adverse effects were noticed during the treatment period. So the trial medicine is safe and easily preparable medicine.

Ingredients of MILAGU LEGIYAM

INTERNAL MEDICINE

Milagu

Akkirakaram

Athimathuram

Seeragam

Elakkai

Kirambu

Vaividangam

Kostam

Sathipathiri

Narukku Moolam

Kalkandu

Thaen

Nei

Ingredients of SEERAGA THYLAM

EXTERNAL MEDICINE

Seeragam

Kostam

Karkadagashingi

Kichilikizhangu

Omam

Arathai

Valuzhuvai

Karboga Arisi

Kadagurohini

Kadukkai Pinchu

Kirambu

Indhuppu

Ennai

Aattupal

INTERNAL MEDICINE

Milagu Legiyam

EXTERNAL MEDICINE

Seeraga Thylam

ANNEXURE - I

PREPARATION AND PROPERTIES OF THE TRIAL DRUG

TRIAL DRUG FOR THE TREATMENT

INTERNAL DRUG: MILAGU LEGIYAM

(Reference:Athmaratchamirtham-Page No:445)

SOURCE OF RAW DRUG:

The drugs for the preparation of trial medicine are purchased from authorised centers. The raw drugs are identified and authenticated by medicinal botanist and staffs of Gunapadam department of government siddha medical college, palay. Then the raw drugs are purified and the trial drug will be prepared in PG Gunapadam lab of GSMC-Palayamkottai.

INGREDIENTS:

1. Milagu (Piper nigrum)	-	100palam (3500grams)
2. Akiragaram (Anacyclus pyrethrum)	-	1palam (35 grams)
3. Athimathuram (Glycyrrizha glabra)	-	1palam (35 grams)
4. Seeragam (Cuminum cyminum)	-	1palam (35 grams)
5. Aelam (Eletaria cardamomum)	-	1palam (35 grams)
6. Kirambu (Syzygium aromaticum)	-	1palam (35 grams)
7. Vaividangam (Emblica ribes)	-	1palam (35 grams)
8. Kostam (Saussuria lappa)	-	1palam (35 grams)
9. Sathipathiri (Myristica fragrans)	-	1palam (35 grams)
10. Narrukku moolam (Piper longum)	-	1palam (35 grams)
11. Karkandu	-	10 palam (350 gram)
12. Then (Honey)	-	1/2padi (700 ml)
13. Nei (Ghee)	-	1 padi (1400 ml)
14. Thaneer (Water)	-	1 Thooni (21.5 lit)

PURIFICATION OF RAW DRUGS

MILAGU	:	Soak in butter milk for 3 days. Then fry the clay plate.
AKIRAKARAM	:	Remove the adulterant and make it to dry on the shade light

SEERAGAM	:	Soak in $Ca(OH)_2$ water on 21 hours then dried in sun light.
KIRAMBU	:	Remove the adulterant and fry it
VAIVIDANGAM	:	Remove the adulterant and make it to dry on the shade light
AELAM	:	Remove the adulterant and fry it
THIPPLI	:	Remove the adulterant and fry it
OMAM	:	Soak in Ca $(OH)_2$ water on 3 hours then sun dried
KOSTAM	:	Just remove the adulterant and make it dry on the shade light
THIPPILI MOOLAM	:	Just remove the adulterant and make it to dry on the sun light.
JATHIPATHIRI	:	Just remove the adulterant and make it to dry on the shade light.

PREPARATION OF THE TRIAL DRUG

Take the above raw drugs are powdered separately except Milagu mixed all together. Add milagu powder to 1 Thooni(21.5Lit.) of water and make Decoction (1:8), 10 palam(350g) of karkandu is added to the above decoction and make the sugar solution. Add the powdered raw drugs to the sugar solution stir well. Add 1padi (1400 ml) nei and stir well until it reaches the required consistency. Add ½ padi (700 ml) honey and stir well. Store it in a separate dry airtight container.

DRUG STORAGE AND DISTRIBUTION:

The trial drug **"MILAGU LEGIYAM"** is stored in clean and dry air tight containers.

- The Legiyam is dispensed in airtight packets
- For Outpatient one packet is given for seven days once. (to be taken twice daily)
- For Inpatient every day the medicine packets will be dispensed in person.

PROPERTIES OF THE INGREDIENTS OF TRIAL DRUG

1.மிளகு:

வேறு பெயர்கள்: கறி, காயம், கோளகம், சருமபந்தம், மாசம், மலையாளி, திரங்கம்.

Botanical Name: Piper nigrum

Family Name: Piperaceae

English Name: Black pepper

Part Used: Dried unripe fruit

சுவை: கைப்பு, கார்ப்பு.

தன்மை: வெப்பம்.

பிரிவு: கார்ப்பு.

செய்கை: வாதமடக்கி, வீக்கங்கரைச்சி.

பொதுகுணம்:

கோணுகின்ற பக்கவலி குய்யவுரோ கம்வாத
சோணிதங்க ழுத்திற்குள் தோன்றுநோய்-காணரிய
காதுநோய் மாதர்குன்மம் காமாலை மந்தமென்றீர்
ஏதுநோய் காயிருக்கில் ஈங்கு.

-தேரையர் குணவாகடம்

Chemical constituents:

Alkaloids-Piperine,piperidine,chavicin (Present in Masocarp), Dipiperamides D&E

2. அக்கிரகாரம்:

வேறு பெயர்கள்: அக்கிரகாரம்

Botanical name: Anacyclus pyrethrum

Family name: Asteraceae

English name: Pelitory

சுவை: கார்ப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

பொதுக்குணம்:

அக்க ரகாரம் அதன்பேர் உரைத்தக்கால்
உக்கிரகால் அத்தோடம் ஓடுங்காண்-முக்கியமாய்க்
கொண்டால் சலம்ஊறும் கொம்பனையே! தாகசுரம்
கண்டால் பயங்ந்தோடுங் காண்

-அகத்தியர் குணவாகடம்

Chemical Constituents: Pellitonin, pyrethrin.

3. அதிமதுரம்

வேறு பெயர்கள்: அதிங்கம், அட்டி, மதூகம், குன்றிவேர்.

Botanical Name: Glycyrrhiza glabra

Family Name: Fabaceae

English Name: Indian liquorice

Part Used: Root

சுவை: இனிப்பு

தன்மை:சீதம்

பிரிவு: இனிப்பு

பொதுக்குணம் :

கத்தியரி முப்பிணியால் வருபுண் தாகங்
கண்ணோய்உன் மாதம்விக்கல் வலிவெண் குட்டம்
பித்தமெலும் புருக்கி கிரிச்சரம் ஆவர்த்த
பித்தமத மூர்ச்சை விட பாகம் வெப்பந்
தத்திவரு வாதசோ ணிதங்கா மாலை
சருவவிடங் காமியநோய் தாது நட்டங்
குத்திருமல் ஆசியங்கம் இதழ்நோய் இந்து
குயப்புணும்போம் மதூகமெனக் கூறுங் காலே.

-தேரையர் குணவாகடம்.

Chemical Constituents: Glycyrrhizin, Asparagin, Sugar, Starch, Acid resin, Gum, Mucilage, Phosphoric, Shulphuric & Malic acid, Calcium & Magnisium Salts.

செய்கை: கோழையற்றி, சிறுநீர் பெருக்கி, மலமிலக்கி, உரமாக்கி.

4. சீரகம்:

வேறு பெயர்கள்: அசை, சீரி, உபகும்பீசம், நற்சீரி, துத்தசாம்பலம், பித்த நாசினி, போசன குடோரி, மேத்தியம்.

Botanical Name: Cuminum cyminum

Family Name: Apiaceae

English Name: Cumin seeds

Part Used: Seeds

சுவை: கார்ப்பு

தன்மை: தட்பம்

பிரிவு: இனிப்பு

பொதுக்குணம் :

வாயுவொடு நாசிநோய் வன்பித்தஞ் சேராது
காயம் நெகிழாது கண்குளிருந் - தூயமலர்க்
காரளகப் பெண்மயிலே! கைகண்ட தித்தனையுஞ்
சீரகத்தை நீதினமுந் தின்

-அகத்தியர் குணவாகடம்

செய்கை: அகட்டுவாய்வகற்றி,வெப்பமுண்டாக்கி,பசித்தீத்தூண்டி.

Chemical Constituents: Essential oil-thymene, cuminol, cumic aldehyde.

5. ஏலம்:

வேறு பெயர்கள்: ஆஞ்சி, கோரங்கம், துடி.

Botanical Name: Elettaria cardamomum.

Family Name: Zingiberaceae

Part used: Fruit

சுவை: கார்ப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

பொதுக்குணம்

தொண்டை வாய்கவுள் தாலுகு தங்களில்
தோன்றும் நோயதி சாரம் மேகத்தால்
உண்டை போல்எழுங் கட்டி கரிச்சரம்
உழலை வாந்தி சிலந்தி விஷஞ்சுரம்
பண்டை வெக்கை விதாகநோய் காசமும்
பாழுஞ் சோமப் பிணிவிந்து நட்டமும்
அண்டை யீளைவன் பித்தம் இவைக்கெல்லாம்
ஆல மாங்கமழ் ஏல மருந்தே.

செய்கை: வெப்பமுண்டாக்கி, அகட்டுவாய்வகற்றி, சிறுநீர்ப்பெருக்கி.

Chemical constituents: Fixed oil, Essential oil, Volatile oil, Terpinyl acetate, Terpineol,Limonene.

6. கிராம்பு

வேறுபெயர்கள்: அஞ்சுகம், உற்கடம் , கருவாய்க்கிராம்பு, சோசம், திரளி, வராங்கம்.

Botanical name: Syzygium aromaticum

Family name: Myrtaceae

English name: Cloves

Part used: Flower

சுவை: கார்ப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

பொதுக்குணம்:

பித்த மயக்கம் பேதியொடு வாந்தியும்போம்
சுத்தவிரத தக்கடுப்புந் தோன்றுமோ-மெத்த
இலவங்கங் கொண்டவருக் கேற் சுகமாகும்
மலமங்கே கட்டுமென வாழ்த்து.

செய்கை: இசிவகற்றி, அகட்டுவாய்வகற்றி, பசித்தீத்தூண்டி.

Chemical Constituents: Essential oil, B-caryophyllene, Eugenyl acetate

7. வாய்விடங்கம்:

வேறுபெயர்கள்: கேரளம் , வர்னனை.

Botanical name	:	Emblica ribes
Family name	:	Primulaceae
English name	:	False black
Part used	:	Dried fruit

சுவை: கைப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

பொதுக்குணம்:

பாண்டுகுட்டம் குன்மம் பருந்தூல நோய்வாதந்
தீண்டு திரிவிடந் சிரந்துண்டம்-பூண்டமடி
நோய்விளங்கக் காட்டாத நுண்கிருமி யாசனப்புண்
வாய்விளங்கங்காட்டவிருமார்.

செய்கை: புழக்கொல்லி, அகட்டுவாய்வகற்றி, வெப்பமுண்டாக்கி.

Chemical constituents: Emblic acid, Tanin, Alkaloids-Cristembine, Vidangin, Emblin.

8. கோஷ்டம்

வேறு பெயர்கள்: குரா, ஒலி.

English name: Costus root

Botanical name: Saussuria lappa

Family name: Asteraceae

Part used: Root

சுவை: கைப்பு, விறுவிறுப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

பொதுக்குணம்:

திட்டிகவுள் அகடுகளஞ் சென்னி நாவாய்
செறிபிணிவெப் பதைப்புதா வர்த்தம் ஊதை
முட்டுயெழு முளைவிரணம் சுவாச காசம்
மூடிகத்தோ டரவுமர விடங்கள் மேகக்
கட்டிஅஜ கல்லிவிட பாகம் பூத
கணம்பால கிரகமொடு தாது நட்டஞ்
சொட்டிவரு பிரமிபித்தம் இவையொ ருங்கே
தொலையும்விர ணாரிக்குச் சுகப்பேரறாமே.

செய்கை: வெப்பமுண்டாக்கி, உரமாக்கி, வெப்பமுண்டாக்கி.

Chemical constituents: Alkaloid-Saussurine, Terpene alcohol, Costol, Costic acid, Aplotaxene, a costene B costene

9. சாதிபத்திரி

வேறு பெயர்கள்: ஜாதிபத்திரி, வசுவாசி.

English name: Arillus of the nut

Botanical name: Myrstica fragrans

Family name: Myrstaceae

Part used: Arill

சுவை: கார்ப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

பொதுக்குணம்:

சாதிதரும் பத்திரிக்குத் தாபச் சுரந்தணியும்
ஓதுகின்ற பித்தம் உயருங்காண்-தாதுவிருத்தி
யுண்டாங் கிரகணியோ டோதக் கழிச்சலறும்
புண்டாங் குறையே பகர்.

Chemical constituents: Fixed oil (Butter of nut mug), Myristicene, Myristirol, Myristic acid, Myristin.

10. திப்பிலி மூலம்:

வேறு பெயர்கள்: கிரந்திகம் , கிரந்திவேர் , கண்டதிப்பிலி, மோடி வேர் , நறுக்குமூலம் , நறுக்கு திப்பிலி.

English name: Long pepper root

Botanical name: Pipper longum

Family name: Piperaceae

Part used: Root

சுவை: கார்ப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

பொதுக்குணம்:

தாகபித்தஞ் சோகந் தணியாச் சுரமிருமல்
மேகங் குரற்கம்மல் மெய்க்கடுப்பும்-ஏகுங்காண்
திப்பிலிமூ லங்ணண்டத் திப்பிலிய தாம்நறுக்குத்
திப்பிலியென் றேயொருக்காற் செப்பு.

Chemical constituents: Piperin, resin, Starch, Gum.

11.ஓமம்:

வேறுபெயர்கள்: அசமோதகம், திப்பியம்.

Botanical name: Trachyspermum ammi.

Family name: Apiaceae

English name: The Bishops seeds

Part used: Seeds

சுவை: கார்ப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

பொதுக்குணம்:

சீதசுரங் காசஞ் செரியாமந் தம்பொருமல்
பேதியிரைச் சலகடுப்பு பேராமம்-ஓதிருமல்
பல்லொடுபல் மூலம் பகமிவைநோ யென்செயுமோ?
சொல்லொடுபம் ஓமமெனச் சொல்.

செய்கை: பசித்தீத்தூண்டி, அழகலகற்றி, வெப்பமுண்டாக்கி, உரமாக்கி, இசிவகற்றி.

Chemical Constituents: Essential oil,Thymol.

11. நெய்:

English Name: Ghee

பொதுக்குணம்:.

தாகமுழ லைகட்கம் வாந்தி பித்தம் வாயுபிர
மேகம் வயிற்றெரிவு விக்கலழல்-மாகாசங்
குன்மம் வறட்சி குடற்புரட்ட லஸ்திகட்கஞ்
சொன்மூலம் போக்கநிறைத் துப்பு.

12. தேன்:

பொதுக்குணம்:

ஆயுளுட னுட்டிணம ரோசி யகக்கபமு
மேய வழகம் வளர்த்திடுங்காண்-தூய
மதிய மெனுவதன மாதரசே நாளும்
புதிய நறுந்தேனாற் புகல்.

சுவை: இனிப்பு

செய்கை: உள்ளாழற்றி, மலமிளக்கி, துவர்ப்பி, அழகலகற்றி, கோழையகற்றி, பசித்தீத்தூண்டி, உரமாக்கி, தூக்கமுண்டாக்கி.

External Medicine:

(Reference:Sarabenthirar vaidya Muraigal)

சீரகத்தைலம்:

கந்தமிகு சீரகம்வா லுளுவைகோட்டங்
கார்போக வரிசிகற் கடகசிங்கி
யிந்துப்புக் கச்சோலங் கடுகுரோகிணி
யெழிலோமங் கிராம்புதுவர்ச் சிகையரத்தை
யிந்தவகை வகையினுக்கோர் கழஞ்சுநாழி
யெண்ணெயுட னாட்டுப்பா னாழிகூட்டி
வெந்தவுட விறுத்துக்கொண் டுடலிற்பூசில்
வெகுவாதந் தீருமீ தறிந்துசெய்யே.

Ingredients:

1. Seeragam (Cuminum cyminum)
2. Kostam (Costus speciousus)
3. Karkadaga Shingi (Rhus succedanea)
4. Kichilik-Kizhangu (Curcuma zedoaria)
5. Omam (Trachyspermum ammi)
6. Arattai (Alpinia galanga)
7. Valuzhuvai (Celastrus painculatus)
8. Karpokarisi (Psoralea corylifolia)
9. Kadugurohini (Picrorhiza kurroa)
10. KadukkaiPinchu (Terminalia chebula)
11. Kirambu (Syzygium aromaticum)
12. Indhuppu (Rock salt)
13. Ennai (Gingley oil)
14. Aattuppaal (Goat milk)

METHOD OF PREPARATION OF SEERAGAM THYLAM

Grind the above raw drugs to powder. Mix the powder with goat milk and oil then boil it. Then filter the oil and kept it in air tight container.

1. சீரகம்

வேறு பெயர்கள்: அசை, சீரி, உபகும்பீசம், நற்சீரி, துத்தசாம்பலம், பித்த நாசினி, போசன குடோரி, மேத்தியம்.

Botanical Name : Cuminum cyminum

Family Name: Apiaceae

English Name: Cumin seeds

Part Used: Seeds

சுவை: கார்ப்பு

தன்மை: தட்பம்

பிரிவு: இனிப்பு

பொதுக்குணம் :

வாயுவொடு நாசிநோய் வன்பித்தஞ் சேராது
காயம் நெகிழாது கண்குளிருந் - தூயமலர்க்
காரளகப் பெண்மயிலே! கைகண்ட தித்தனையுஞ்
சீரகத்தை நீதினமுந் தின்

-அகத்தியர் குணவாகடம்

செய்கை: அகட்டுவாய்வகற்றி,வெப்பமுண்டாக்கி,பசித்தீத்தூண்டி.

Chemical Constituents: Essential oil-thymene, cuminol, cumic aldehyde.

2. கோஷ்டம்

வேறு பெயர்கள்: குரா, ஒலி.

English name: Costus root

Botanical name: Saussuria lappa

Family name: Asteraceae

Part used: Root

சுவை: கைப்பு, விறுவிறுப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

பொதுக்குணம்:

திட்டிகவுள் அகடுகளஞ் சென்னி நாவாய்
செறிபிணிவெப் பதைப்புதா வர்த்தம் ஊதை
முட்டுயெழு முளைவிரணம் சுவாச காசம்
மூடிகத்தோ டரவுமர விடங்கள் மேகக்
கட்டிஅஜ கல்லிவிட பாகம் பூத
கணம்பால கிரகமொடு தாது நட்டஞ்
சொட்டிவரு பிரமிபித்தம் இவையொ ருங்கே
தொலையும்விர ணாரிக்குச் சுகப்பேரறாமே.

செய்கை: வெப்பமுண்டாக்கி, உரமாக்கி

Chemical constituents: Alkaloid-Saussurine,Terpene alcohol,Costol, Costic acid, Aplotaxene, a costene B costene.

3. கர்கடகசிங்கி:

வேறுபெயர்கள்: கற்காடகசிங்கி

Botanical name: Rhus succedanea.

Family name: Anacardiaceae.

English name: Gall.

Part used: Gall.

சுவை: துவர்ப்பு

தன்மை: கார்ப்பு

பிரிவு: கார்ப்பு

பொதுக்குணம்:

கர்கடக சிங்கி கபங்காசம் ஈளையொடு
முக்கல் கிராணி முதிரிரைச்சல்-பொக்கெனவே
சாடுகின்ற பேதியையுஞ் சாடும் அரிவையரைக்
கூடுதிறங் கொடுக்குங் கூறு.

செய்கை: துவர்ப்பி, உரமாக்கி, வெப்பமுண்டாக்கி.

Chemical Constituents: Essential oil,Tannin.

4. கிராம்பு

வேறுபெயர்கள்: அஞ்சுகம் , உற்கடம், கருவாய்க்கிராம்பு, சோசம், திரளி, வராங்கம்.

Botanical name: Syzygium aromaticum

Family name: Myrtaceae

English name: Cloves

Part used: Flower

சுவை: கார்ப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

பொதுக்குணம்:

பித்த மயக்கம் பேதியொடு வாந்தியும்போம்
சுத்தவிரத தக்கடுப்புந் தோன்றுமோ-மெத்த
இலவங்கங் கொண்டவருக் கேற் சுகமாகும்
மலமங்கே கட்டுமென வாழ்த்து.

செய்கை: இசிவகற்றி, அகட்டுவாய்வகற்றி, பசித்தீத்தூண்டி..

Chemical Constituents: Essential oil,B-caryophyllene,eugenyl acetate.

5. கிச்சிலிக்கிழங்கு

வேறுபெயர்கள்: பூலாங்கிழங்கு, கச்சோலம், கர்ச்சூரம்.

Botanical name: Curcuma zedoria

Family name: zingiberaceae

English name: Round zedory

Part used: Tubers

சுவை: கைப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

பொதுக்குணம்:

(ஒட்டும்)நற் கிச்சிலியி ணொண்கிழங் குங்கபமும்
பூட்டுமுட மும்புண்ணும் போம்.

செய்கை: வெப்பமுண்டாக்கி, அகட்டுவாய்வகற்றி, பசித்தீத்தூண்டி.

Chemical Constituents: Organic acids, Cumin arabins, Albuminoids,essential oil.

6. ஓமம்:

வேறுபெயர்கள்: அசமோதம் , திப்பியம்.

Botanical name: Trachyspermum ammi

Family name: Apiaceae

English name: Bishop's weed

Part used: Seeds

சுவை: கார்ப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

பொதுக்குணம்:

சீதசுரங் காசஞ் செரியாமந் தம்பொருமல்
பேதியிரைச் சல்கடுப்பு பேராமம்-ஓதிருமல்
பல்லொடுபல் மூலம் பகமிவைநோ யென்செயுமோ?
சொல்லொடுபோம் ஓமமெனச் சொல்.

செய்கை: பசித்தீத்தூண்டி, அழகலகற்றி, உரமாக்கி, வெப்பமுண்டாக்கி, அகட்டுவாய்வகற்றி, இசிவகற்றி.

Chemical Constituents: Essential oil,Thymol

7.அரத்தை

வேறுபெயர்கள்: சிற்றரத்தை

Botanical name: Alpinia galanga

Family name: Zingiberaceae

English name: Java galangal

Part used: Rhizome

சுவை: கார்ப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

பொதுக்குணம்:

தொண்டையிற்கட் டுங்கபத்தைத் துரத் துரத்திவிடும்
பண்டைச்சீ தத்தைப் பறக்கடிக்கும்-கெண்டைவிழி

மின்னே! கரப்பனைவே றாக்கும் பசிகொடுக்கும்
சொன்னோம் அரத்தைச் சுகம்

செய்கை: கோழையகற்றி, வெப்பகற்றி, பசித்தீத்தூண்டி.

Chemical Constituents: Campheride, Glangin and Alpinin

8. வாலுளுவை:

வேறுபெயர்கள்: கங்குணி, மால்கங்குணி, அதிபறிச்சம்.

Botanical name: Celastraus paniculatus

Family name: Celastraceae

English name: Climbing staff plant

Part used: Seeds

சுவை: கைப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

பொதுக்குணம்:

வயிற்றுக் கடுப்புவலி மாறாக் கிராணி
பயித்திங் காசமல பந்தஞ்- சயிக்கவொணாச்
சூதிகா வாதமும் போந் தொல்வா லுளுவைவிதைக்
குாதிநவ சித்தர் யாம்.

செய்கை: வெப்பமுண்டாக்கி, வியர்வைபெருக்கி, நாடியுரமாக்கி, உடற்தேற்றி, காமம்பெருக்கி.

Chemical Constituents: Tannin

9. கார்போகரிசி

வேறுபெயர்கள்: கார்புவா அரிசி, பாகுசி.

Botanical name: Psoralea corylifolia

Family name: Fabaceae

English name: Babchi Seeds

Part used: Seeds

சுவை: கைப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

பொதுக்குணம்:

கார்போக மாமரிசி கண்டாற் கரப்பான்புண்
பீர்சகுவ நஞ்சிவைபோம் பித்தமுண்டாம்- பார்மீதில்

வாத கபநமைச்சல் வன்சொறிசி ரங்குமறுஞ்
சீத மலர்க்குழாய் செப்பு.

செய்கை: மலமிளக்கி, வெப்பமுண்டாக்கி.

Chemical Constituents: Essential oil,Albumin,Sugar,Magnese

10. கடுகுரோகிணி

வேறுபெயர்கள்: கடுரோகிணி, கடகரோகிணி.

Botanical name: Picrorhiza kurroa.

Family name: Plantaginaceae.

English name: Green Hellbore Rhizome.

Part used: Rhizome

பொதுக்குணம்:

மாந்தஞ் சுரமையம் வாயுசுரப் பானாமஞ்
சேர்ந்தமலக் கட்டு திரிதோடம்- போந்தபொட்டுப்
புண்வயிறு நோயிவைபோம் பொற்கொடியே- பேதியுண்டாம்
திண்கடுகு ரோகணிக்குத் தேர்

செய்கை: முறைவெப்பகற்றி, பெருங்கழிச்சலுண்டாக்கி, பசித்தீத்தூண்டி, குடற்புழுவகற்றி.

Chemical Constituents: Wax, Cathartic acid,Glucoside-picorrhizin,Glucose.

11. கடுக்காய்பிஞ்சு:

வேறுபெயர்கள்: அரிதகி, அபையன், பத்தியம், அமுதம், அவ்வியதா, சேதகி, வனதுர்க்கி,சேதகி, அந்தன், அலியன், அம்ருதா, கடு, சிவா, ரோகிணி, மேகம்.

Botanical name: Terminalia chebula.

Family name: Combretaceae.

English name: Chebulic Myrobalam Ink nut.

Part used: Dried immature fruit.

சுவை: துவர்ப்பு, இனிப்பு, புளிப்பு, கார்ப்பு, கைப்பு.

தன்மை: வெப்பம்.

பிரிவு: இனிப்பு

பொதுக்குணம்:

தாடை கழுத்தக்கி தாலு குறியிவிடப்
பீடை சிலிபதமுற் பேதிமுடம்- ஆடையெட்டாத்
தூலமிடி புண்வாத சோணிகா
டாலமிடி போம்வரிக்கா யால்.

செய்கை:

Chemical Constituent: Astringent, Tannic acid,Gallic acid,Chebulinic acid

12.இந்துப்பு

வேறுபெயர்கள்: சைந்தவம், சிந்தூரம் , சந்திரனுப்பு, மதிகூர்மை, மதியுப்பு, மிந்தாச்சொல்.

English name: Sodium chloride lmpura

பொதுக்குணம்:

"அட்டகுன்ம மந்தம் அசிர்க்கரஞ்சூர் சீதபித்தந்
துட்வையம் நாடிப்புண் டோடங்கள்-கெட்டமலக்
கட்டுவிட விந்தையக் காமியநோய் வன்கரப்பான்
விட்டுவிட விந்துப்பை விள்."

செய்கை: மலமிளாக்கி, அகட்டுவாய்வகற்றி, சிறுநீர்பெருக்கி, பசித்தீத்தூண்டி.

Chemical Constituents:

13. எள்ளின் நெய்:

Botanical name: Sesamum indigum

Family name: Pedaliaceae

English name: Gingley oil

Part used: Seeds.

செய்கை: மலமிளக்கி, உள்ளழாற்றி, ருதுவுண்டாக்கி, பாற்பெருக்கி.

Chemical Constituents: 70%liquids,60% of glycosides of olecacid,linoleic acid,fats,stearin,palmitin.

14. ஆட்டுப்பால்

Zoological name: Capra aegagrus hircus

பொதுகுணம்:

வெள்ளாட்டு பாலுக்குமேவியநற் றீபனமாந்
தள்ளாடு வாதபித்தஞ் சாந்தமாம்-உள்ளிரைப்புச்
சீதமதி சாரஞ் சிலேஷ்மமமறும் புண்ணாறும்
வாத சிலேஷ்மமுப்போ மாய்ந்து.

Chemical constituents; β-lactalbulin, χ-casein, αs2- casein, potassium, chloride, vitamin B6 and vitamin B12.

ANNEXURES -II

QUALITATIVE AND QUANTITATIVE ANALYSIS

BIO-CHEMICAL ANALYSIS OF MILAGU LEGIYAM (IN POWDER FORM)

Preparation of the extract:

5gms of the drug was weighed accurately and placed in a 250ml clean beaker. Then 50ml of distilled water is added and dissolved well. Then it is boiled well for about 10 minutes. It is cooled and filtered in a 100ml volumetric flask and then it is made to 100ml with distilled water. This fluid is taken for analysis.

QUALITATIVE ANALYSIS

S.NO	EXPERIMENT	OBSERVATION	INFERENCE
1.	**TEST FOR CALCIUM** 2ml of the above prepared extract is taken in a clean test tube. To this add 2ml of 4% Ammonium oxalate solution.	A white precipitate is formed.	**Indicates the presence of calcium.**
2.	**TEST FOR SULPHATE** 2ml of the extract is added to 5% Barium chloride solution.	A white precipitate is formed.	**Indicates the presence of sulphate.**
3.	**TEST FOR CHLORIDE** The extract is treated with silver nitrate solution.	A white precipitate is formed.	**Indicates the presence of chloride.**
4.	**TEST FOR CARBONATE** The substance is treated with concentrated HCL.	No Brisk effervescence is formed	Absence of carbonate
5.	**TEST FOR STARCH** The extract is added with weak iodine solution.	No Blue colour is formed.	Absence of starch.
6.	**TEST FOR FERRIC IRON** The extract is acidified with Glacial acetic acid and potassium ferro cyanide.	No blue colour is formed.	Absence of ferric iron.
7.	**TEST OF FERROUS IRON** The extract is treated with concentrated Nitric acid and Ammonium thio cyanide solution.	Blood red colour is formed.	**Indicates the presence of ferrous iron.**

8.	**TEST FOR PHOSPHATE** The extract is treated with Ammonium Molybdate and concentrated nitric acid.	No yellow precipitate is formed.	Absence of phosphate.
9.	**TEST FOR ALBUMIN** The extract is treated with Esbach's reagent.	No Yellow precipitate is formed.	Absence of Albumin.
10.	**TEST FOR TANNIC ACID** The extract is treated with ferric chloride.	No Blue black precipitate is formed.	Absence of tannic acid.
11.	**TEST FOR UNSATURATION** Potassium permanganate solution is added to the extract.	It gets decolourised.	**Indicates the presence of unsaturated compound.**
12.	**TEST FOR THE REDUCING SUGAR** 5ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 mts and add 8-10 drops of the extract and again boil it for 2 minutes.	Colour change occurs.	**Indicates the presence of Reducing sugar.**
13.	**TEST FOR AMINO ACID** One or two drops of the extract is placed on a filter paper and dried well. After drying, 1% Ninhydrin is sprayed over the same and dried it well.	Violet colour is formed.	**Indicates the presence of Amino acid.**
14.	**TEST FOR ZINC** The extract is treated with Potassium Ferrocyanide.	No white precipitate is formed	Absence of Zinc.

Inference:

The given sample of "MILAGU LEGIYAM" contains Calcium, Sulphate, Chloride, Ferrous iron, Unsaturated compound, Reducing sugar, Amino acid.

PHARMACOLOGICAL ANALYSIS

EFFECT OF MILAGU LEGIYAM WITH HONEY/GHEE ON CARRAGEENAN-INDUCED LOCALISED INFLAMMATORY PAIN IN RATS

SUMMARY

The study plan was developed based on the guidelines of Vogel[1] and also it has reference to Chao Ma and Jun-Ming Zhang[2] and Walker et al. [3,] Winter CA, Risley EA, Nuss GW. Carrageenin induced edema in hind paw of the rat as an assay for anti-inflammatory drugs. Proc Soc Exp Biol Med. 1962;111:544–7.

Objective

To study the anti-inflammatory effect of **MILAGU LEGIYAM** were prepared **WITH HONEY/GHEE** in the rat model of Carrageenan-induced localized inflammation.

Methods:

Test System

Species	:	Rat
Strain	:	Albino Wister
Age	:	6-8 weeks at the time of dosing
Total no. of Rats	:	24
Sex	:	Male
Weight	:	150 gm

The animals were housed in polypropylene cages with stainless steel top grills having facilities for holding pellet food and drinking water in bottle with stainless steel sipper tube. Each cage contained 6 rats. All rats had free access to potable water and standard pelleted laboratory animal diet *ad libitum*. Paddy husk was used as bedding material. The animals were divided into 5 groups (6 rats/group). Localized inflammatory pain was induced in all groups of animals by intraplantar injection of carrageenan (50 µl of 3% suspension).

One day before the experiment, three basal readings of hind paw in each rat were recorded. Group 1 received vehicle orally, Group 2 received a standard drug Diclofenac sodium (10 mg/kg i.p), whereas groups 3,4and 5 received **MILAGU LEGIYAM**. The doses of **MILAGU LEGIYAM** were prepared **WITH HONEY/GHEE**, whereas Diclofenac sodium was dissolved in normal saline. After 30 min, the rats were challenged with subcutaneous

injection of 0.1 ml of 1% w/v solution of carrageenan into the sub plantar region of left paw. The paw was marked with ink at the level of lateral malleolus and immersed in mercury up to the mark. The paw volume was measured at 0, 1, 2, 3, 4, 5 and 6^{th} hr after carrageenin injection using Digital Plethysmometer. The difference between initial and subsequent reading gave the actual edema volume.

DOSAGE SCHEDULE:

The required dose for mice/rat will be calculated by using the standard dose calculation procedure from recommended clinical dose.

CONVERSION FORMULA:

Human dose is 6000 mg /kg day

Total clinical dose (a) x conversion factor (b) 0.018 = (c) per 150 gm of Rat

6000 mg x 2(a) x 0.018 (b) = 108 (c) /150 gm of Rat

108/1000x150 = 16.2 mg

Experimental Doses Calculated as per the standard procedures are

S.No	Groups	Dose /kg, weight	Volume of administration
1	Vehicle Control	--	1 ml
2	Therapeutic Dose	16.2 mg /kg	1 ml
3	Middle Dose	81mg/kg	1 ml
4	High Dose	405mg/kg	1 ml

EXPERIMENTAL DESIGN:

Group-I: Served as a negative control (0.1ml of 1% carrageenin)

Group-II: Served as standard received Diclofenac sodium (10mg/kg, i.p) + (0.1ml of 1% carrageenin)

Group-III: Received **MILAGU LEGIYAM** were prepared **WITH HONEY/GHEE** (16.2 mg /kg) + (0.1ml of 1% carrageenin)

Group IV: Received **MILAGU LEGIYAM** were prepared **WITH HONEY/GHEE** (81 mg/kg) + (0.1ml of 1% carrageenin)

Group V: Received **MILAGU LEGIYAM** were prepared **WITH HONEY/GHEE** (405 mg/kg) + (0.1ml of 1% carrageenin)

TABLE: EFFECT OF MILAGU LEGIYAM WITH HONEY/GHEE ON Carrageenin -INDUCED PAW EDEMA IN RATS- BODY WEIGHT in gms

Group	Only Carrageenan	Carrageenan+ Diclofenac 10mg/kg	Carrageenan+ ML L.D	Carrageenan +ML M.D	Carrageenan+ ML H.D
INITIAL BODY WEIGHT	134±1.155	136±4	146.3±2.028*	144.7±1.764*	135.7±2.028

Values are expressed as the mean ± S.D. Statistical significance (p) calculated by one way ANOVA followed by dunnett's. ns- not significant $^{**}P< 0.05$ calculated by comparing treated group with control group

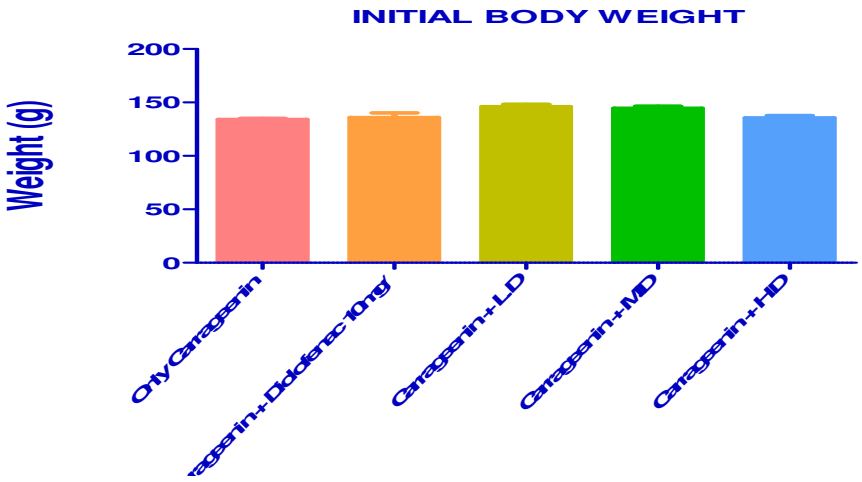


TABLE: EFFECT OF MILAGU LEGIYAM WITH HONEY/GHEE ON Carrageenin -INDUCED PAW EDEMA IN RATS

Group	Mean paw volume before carrageenan injection	Paw Volume after induction with carrageenin Increase in paw volume (ml) after carrageenan injection (mean ± SEM)			Paw Volume after induction with carrageenin Increase in paw volume (ml) after carrageenan injection (mean ± SEM)			
	0 min	30 min	1hr	2hr	3h	4h	5h	6h
Only Carrageenan	3.497± 0.1225	7.163± 0.4528	7.847 ± 0.2384	8.167 ± 0.1348	8.447 ± 0.05925	8.447± 0.04055	8.23± 0.04726	8.093± 0.05207
Carrageenan + Standard	3.367± 0.07424	6.72± 0.302***	7.8± 0.1908	7.2± 0.0611*	7.203 ± 0.1317*	6.873± 0.02906***	6.54± 0.1724***	5.993± 0.07513***
Carrageenan + ML L.D	3.237± 0.133	7.06± 0.1026***	7.587 ± 0.1683	8.337 ± 0.2992	8.333 ± 0.4807	8.16± 0.1405	7.967± 0.07688	7.44± 0.2948
Carrageenan + ML M.D	3.427± 0.2483	6.92± 0.04619***	7.353 ± 0.07055	7.533 ± 0.2969	7.113 ± 0.0636**	7.193± 0.2136***	6.44± 0.04619***	5.973± 0.07424***
Carrageenan +ML H.D	4.133± 0.1618	7.093± 0.1122***	7.3± 0.151	7.2± 0.1405*	7.06± 0.1361**	6.88± 0.08327***	6.26± 0.1311***	5.587± 0.208***

Values are expressed as the mean ± S.D. Statistical significance (p) calculated by one way ANOVA followed by dunnett's. ns- not significant $^{**}P< 0.05$ calculated by comparing treated group with control group

EFFECT OF MILAGU LEGIYAM WITH HONEY/GHEE ON Carrageenin -INDUCED PAW EDEMA IN RATS

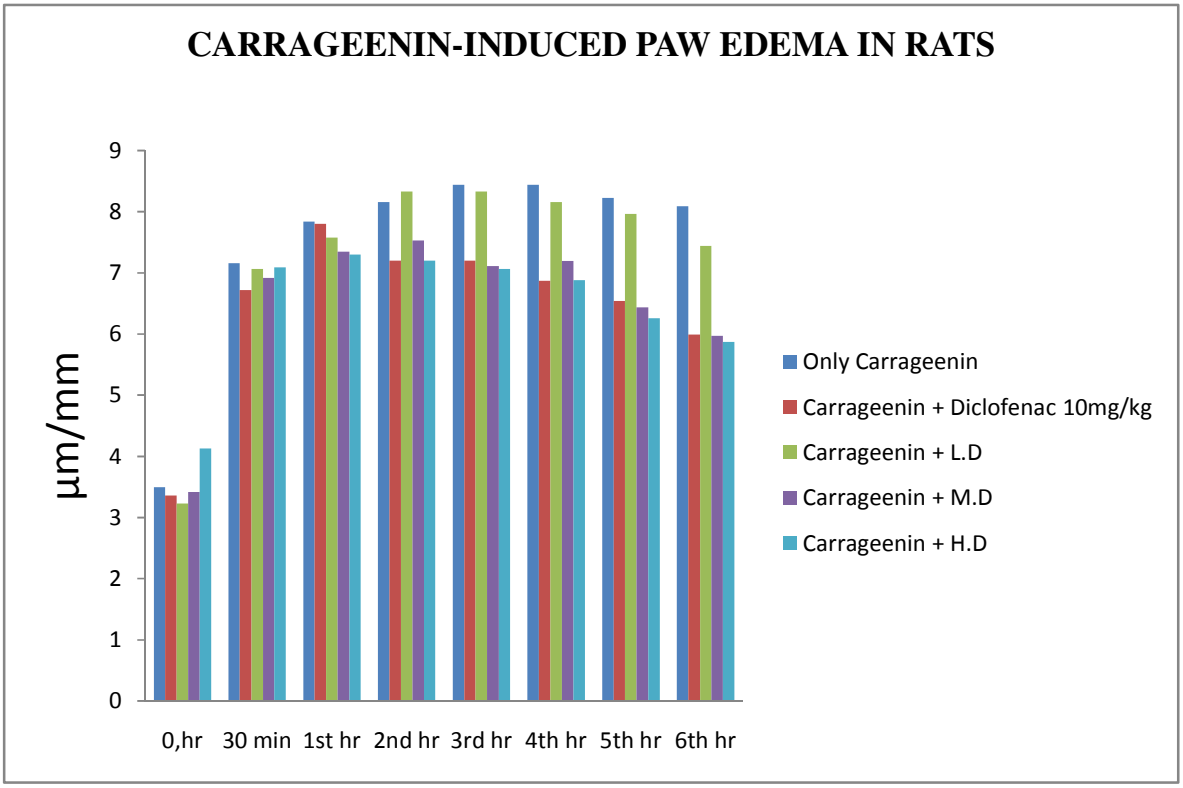


FIG- EFFECT OF MILAGU LEGIYAM WITH HONEY/GHEE ON Carrageenin - INDUCED PAW EDEMA IN RATS

Only Carrageenin

Carrageenin+ STD

Carrageenin +ML L.D

Carrageenin+ ML M.D

Carrageenin+ ML H.D

EFFECT OF MILAGU LEGIYAM WITH HONEY/GHEE ON ACETIC ACID INDUCED WRITHING IN MICE[1]

1. Kaneria MS, Naik SR, Kohli RK. Anti-inflammatory,antiarthritic and analgesic activity of a herbal formulation. Indian J.Experimental Biol. 2007; 45: 279.

Acetic acid induced writhing method was adopted for evaluation of analgesic activity. Writhing is defined as a stretch, tension to one side, extension of hind legs, contraction of the abdomen so that the abdomen of mice touches the floor, turning of trunk (twist). Any writhing is considered as a positive response.

MATERIAL AND METHODS

ANIMALS:

Healthy Swiss albino rats of either sex weighing 20-25g were used in this study. All the animals were obtained from Animal house of the KMCH College of Pharmacy, Coimbatore. The animals were housed comfortably in a group of six in a single clean plastic cage with a metal frame lid on its top. They were housed under standard environmental conditions of temperature (24±1°C) and relative humidity of 30-70 %. A 12:12 h light dark cycle was followed. All animals had free access to water and standard pelletized laboratory animal diet ad libitum. All the experimental procedures and protocols used in this study were reviewed and approved via the Approval No. ---------- by the Institutional Animal Ethical Committee (IAEC) of KMCH College of Pharmacy, Coimbatore (685/PO/Re/S/2002/CPSCEA Dated 21st August 2002 constituted in accordance with the guidelines of the CPCSEA, Government of India.

DRUGS:

Acetic acid (Sigma Chemical Co. Bangalore, India) and Indomethacin were purchased from (Ranbaxy, India). All drugs were dissolved in saline. The different doses of **VATHATHIRKU LEGHIYAM** were prepared **WITH HONEY/GHEE**.The control group received vehicle as control. All drugs were prepared just before use.

PREPARATION OF ACETIC ACID:

A solution of acetic acid (1% v/v) in distilled water was prepared.

DOSAGE SCHEDULE:

The required dose for mice/rat will be calculated by using the standard dose calculation procedure from recommended clinical dose.

CONVERSION FORMULA:

Human dose is 6000 mg /kg day

Total clinical dose (a) x conversion factor (b) 0.018 = (c) per 30 gm of mice

6000 mg x 2(a) x 0.018 (b) = 108 (c) /30 gm of mice

108/1000x30 = 3.24 mg

Experimental Doses Calculated as per the standard procedures are

S.No	Groups	Dose /kg, weight	Volume of administration
1	Vehicle Control	--	0.5 ml
2	Therapeutic Dose	3.24 mg /kg	0.5 ml
3	Middle Dose	16.2mg/kg	0.5 ml
4	High Dose	81mg/kg	0.5 ml

EXPERIMENTAL PROCEUDRE:

GROUP 1 – CONTROL (IP injection of 0.1 ml 1% acetic acid)

GROUP 2 -- IP injection of 0.1 ml 1% acetic acid + Indomethacin (5mg/kg, i.p)

GROUP 3 -- 0.1 ml 1% acetic acid (ip) + **MILAGU LEGIYAM WITH HONEY/GHEE 3.24mg /kg(po)**

GROUP 4 -- 0.1 ml 1% acetic acid (ip) + **MILAGU LEGIYAM WITH HONEY/GHEE 16.2mg/kg(po)**

GROUP 5 -- 0.1 ml 1% acetic acid (ip) + **MILAGU LEGIYAM WITH HONEY/GHEE 81mg/kg(po)**

PROCEDURE:

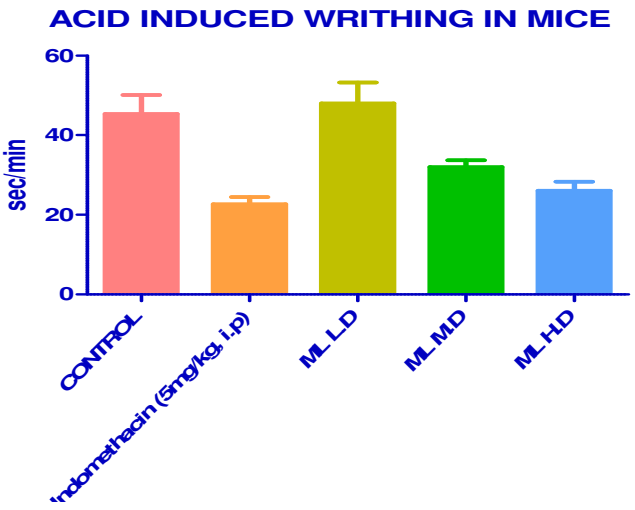
Wister albino mice of either sex were divided into five different groups each containing Six animals, the animals were marked individually. Food was withdrawn 12 hours prior to drug administration till completion of experiment. The animals were weighed and numbered appropriately. The test and standard drugs were given orally. After 60 minutes writhing was induced by intra-peritoneal injection of 1% acetic acid in volume of 0.1 ml/10g body weight. The writhing episodes were recorded for 30 minutes; stretching movements consisting of arching of the back, elongation of body and extension of hind limbs were counted.

Anti-nociceptive activity was expressed as the percentage inhibition of abdominal constrictions using the ratio: (Control mean – Treated mean) × 100/Control mean

EFFECT OF MILAGU LEGIYAM WITH HONEY/GHEE ON ACETIC ACID INDUCED WRITHING IN MICE[1]

GROUP	No of Writhing (30min)	Inhibition (%)
CONTROL	45.33±4.807	---
Indomethacin (5mg/kg, i.p)	22.67±1.764***	49.98 %
ML+ LOW DOSE **0.028mg/kg(po)**	48±5.292	5.89 %
ML + MIDDLE DOSE **0.014mg/kg(po)**	32±1.732	29.40 %
ML + HIGH DOSE **0.28mg/kg(po)**	26±2.309	42.64 %

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.



EFFECT OF MILAGU LEGIYAM WITH HONEY/GHEE ON HOT PLATE METHOD IN MICE[1]

1. Turner RA. Screening methods in pharmacology. In: Turner, R., Hebborn, P. (eds.). Academic press, New York. 1965; 100.

The paws of mice and rats are very sensitive to heat at temperatures which are not damaging the skin. The responses are jumping, withdrawal of the paws and licking of the paws.

MATERIAL AND METHODS

ANIMALS:

Healthy Swiss albino rats of either sex weighing 20-25g were used in this study. All the animals were obtained from Animal house of the KMCH College of Pharmacy, Coimbatore. The animals were housed comfortably in a group of six in a single clean plastic cage with a metal frame lid on its top. They were housed under standard environmental conditions of temperature (24±1°C) and relative humidity of 30-70 %. A 12:12 h light dark cycle was followed. All animals had free access to water and standard pelletized laboratory animal diet ad libitum. All the experimental procedures and protocols used in this study were reviewed and approved via the Approval No. ---------- by the Institutional Animal Ethical Committee (IAEC) of KMCH College of Pharmacy, Coimbatore (685/PO/Re/S/2002/CPSCEA Dated 21st August 2002 constituted in accordance with the guidelines of the CPCSEA, Government of India.

The hot plate, which is commercially available, consists of a electrically heated surface. The temperature is controlled for 55° to 56 °C. This can be a copper plate or a heated glass surface. The animals are placed on the hot plate and the time until either licking or jumping occurs is recorded by a stop-watch.

EXPERIMENTAL PROCEUDRE:

GROUP 1 – CONTROL

GROUP 2 – Pentazocine (10mg/kg, I.P)

GROUP 3 -- MILAGU LEGIYAM WITH HONEY/GHEE

3.24 mg /kg(po)

GROUP 4 – MILAGU LEGIYAM WITH HONEY/GHEE

16.2mg/kg(po)

GROUP 5 -- MILAGU LEGIYAM WITH HONEY/GHEE

81mg/kg(po)

PROCEUDRE:

Mice were screened by placing them on a hot plate maintained at 55±1℃ and recording the reaction time in seconds for forepaw licking or jumping. Only mice which reacted within 15sec and which did not show large variation when tested on four separate occasions, each 15min apart, were taken for the test. The time for forepaw licking or jumping on the heated plate of the analgesiometer maintains at 55ºC was taken as the reaction time. Prior to treatment, the reaction time of each mouse (licking of the forepaws or jumping response) was done at 0- and 10-min interval. The average of the two readings was obtained as the initial reaction time (*Tb*). The reaction time (*Ta*) following the administration of the ----------, Pentazocine and distilled water was measured at 0.5, 1, 2, and 3h after latency period of 30min.

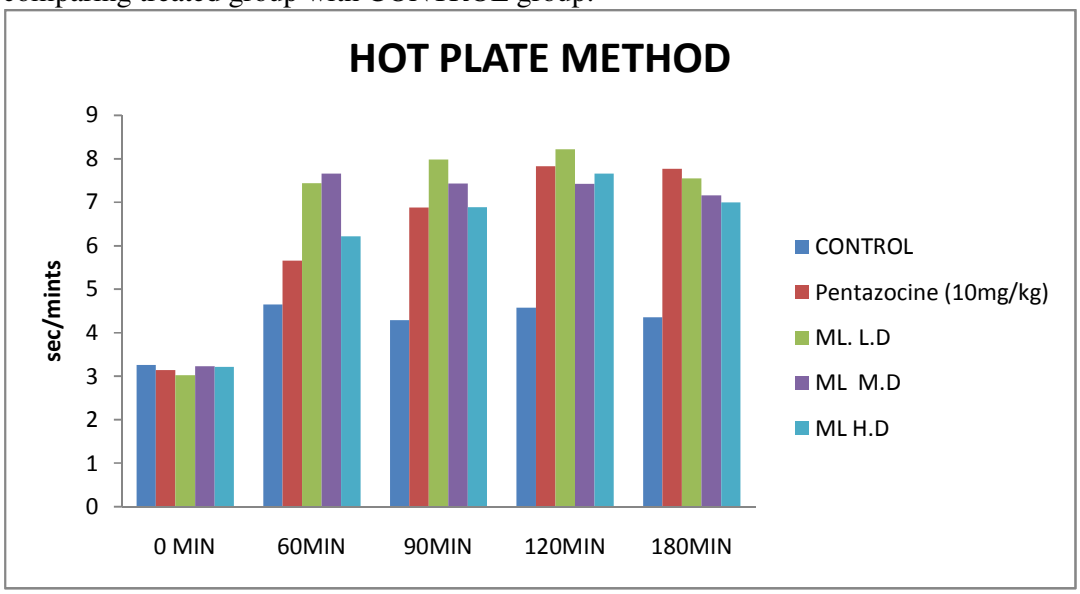
The following calculation was:

Percentage analgesic activity = $Ta\text{-}Tb/Tb \times 100$

EFFECT OF MILAGU LEGIYAM WITH HONEY/GHEE ON HOT PLATE METHOD IN MICE

GROUP	Reaction time in seconds at time (minutes) (mean ± sem) (mean ± sem)				
	O mints	60 mints	90 mints	120 mints	180 mints
CONTROL	3.26±0.0660	4.65±0.138	4.29±0.0683	4.58±0.085	4.36±0.136
STANDARD	3.14±0.0918	5.66±0.049***	6.88±0.149***	7.83±0.106***	7.77±0.146***
ML + LOW DOSE	3.02±0.0143	7.44±0.061***	7.98±0.118***	8.22±0.169***	7.55±0.055***
ML + MIDDLE DOSE	3.23±0.0409	7.66±0.072***	7.43±0.118***	7.42±0.124***	7.16±0.132***
ML + HIGH DOSE	3.22±0.137	6.22±0.108***	6.89±0.084***	7.66±0.073***	7.0±0.157****

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's $^{***}P< 0.001$, $^{**}P < 0.01$, $^{*}P < 0.05$ calculated by comparing treated group with CONTROL group.



ACUTE TOXICITY STUDY IN FEMALE WISTER RATS TO EVALUATE TOXICITY PROFILE OF MILAGU LEGIYAM WITH HONEY/GHEE

Table 1. Test substance details

Name of the test substance	**MILAGU LEGIYAM**
Colour of the test substance	-Light brown
Nature of the test substance	Powder

Table 2. Experimental protocol

Name of the study	Acute toxicity
Guideline followed	OECD 423 method-acute toxic class method
Animals	Healthy young adult female wister rats, nulliparous, non-pregnant
Body weight	150-200 g
Sex	female
Administration of dose and volume	6000 mg/kg in 200g body weight, single dose in 1 ml
Number of groups and animals	5 groups and 3 animals in each group 1000,2000,3000,5000and 6000mg/kg
Route of administration	Oral Cavage (po)
Vechicle	Honey/Ghee

Table3. Housing and feeding conditions

Room temperature	22°C ± 3°C
Humidity	40-60%
Light	12 h : 12h (light : dark cycle)
Feed	Standard laboratory animal food pellets with water *ad libitum*

Table 4. Study period and observation parameters

Initial once observation	First 30 minutes and periodically 24 h
Special attention	First 1-4 h after drug administration
Long term observation	Upto 14 days
Direct observation parameters	Tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma.
Additional observation parameters	Skin and fur, eyes and mucous membrane, respiratory, circulatory, autonomic and central nervous systems, somato motor activity and behavior pattern etc.

The time of death, if any, is recorded. (Complete observations: annexure I). After administration of the drug, food is withheld for a further 1-2 hours.

Study procedure

Acute oral toxicity was performed as per organization for economic co-operation for development (OECD) guideline 423 method. The **MILAGU LEGIYAM WITH HONEY/GHEE** was administered in a single dose by tuberculin syringe. Animals are fasted 3 h prior to dosing (food was withheld for 3 h but not water). Following the period of fasting animals was weighed and test substance was administered orally at a dose of 1000,2000,3000,5000 and 6000mg/kg. After the **MILAGU LEGIYAM WITH HONEY/GHEE** administration, food was withheld 2 h in mice. Animals are observed individually after at least once during the first 30 minutes, periodically during the first 24 hrs, with special attention given during the first 4 hrs, and daily thereafter, for a total of 14 days.

REPORT

Toxicological evaluation of MILAGU LEGIYAM WITH HONEY/GHEE

Table:5 Effect of **MILAGU LEGIYAM With Honey/Ghee** on acute toxicity test in female rats.

S.N	Response	Head		Body		Tail	
		Before	**After**	**Before**	**After**	**Before**	**After**
1	Alertness	Normal	Normal	Normal	Normal	Normal	Normal
2	Grooming	Absent	Absent	Absent	Absent	Absent	Absent
3	Touch response	Absent	Absent	Absent	Absent	Absent	Absent
4	Torch response	Normal	Normal	Normal	Normal	Normal	Normal
5	Pain response	Normal	Normal	Normal	Normal	Normal	Normal
6	Tremors	Absent	Absent	Absent	Absent	Absent	Absent
7	Convulsion	Absent	Absent	Absent	Absent	Absent	Absent
8	Righting reflux	Normal	Normal	Normal	Normal	Normal	Normal
9	Gripping strength	Normal	Normal	Normal	Normal	Normal	Normal
10	Pinna reflux	Present	Present	Present	Present	Present	Present
11	Corneal reflux	Present	Present	Present	Present	Present	Present
12	Writhing	Absent	Absent	Absent	Absent	Absent	Absent
13	Pupils	Normal	Normal	Normal	Normal	Normal	Normal
14	Urination	Normal	Normal	Normal	Normal	Normal	Normal
15	Salivation	Normal	Normal	Normal	Normal	Normal	Normal
16	Skin colour	Normal	Normal	Normal	Normal	Normal	Normal
17	Lacrimation	Normal	Normal	Normal	Normal	Normal	Normal

RESULT:

From acute toxicity study it was observed that the administration of **MILAGU LEGIYAM WITH HONEY/GHEE** to Female Wister rats did not induce drug-related toxicity and mortality in the animals up to 6000mg/kg in 200g female Wister rats. So No-Observed-Adverse-Effect- Level (NOAEL) of **MILAGU LEGIYAM with Honey/Ghee** is 6000 mg/kg equal to human dose

DISCUSSION

MILAGU LEGIYAM WITH HONEY/GHEE was administered single time at the doses of 1000,2000,3000,5000 and 6000mg/kg to female Wister rats and observed for consecutive 14 days after administration. Doses were selected based on the pilot study and literature review. All animals were observed daily once for any abnormal clinical signs. Weekly body weight and food consumption were recorded. No mortality was observed during the entire period of the study. Data obtained in this study indicated no significance physical and behavioral signs of any toxicity due to administration of **MILAGU LEGIYAM WITH HONEY/GHEE** at the doses of 1000,2000,3000,5000 and 6000mg/kg to female Wister rats

At the 14th day, all animals were observed for functional and behavioral examination. In functional and behavioral examination, home cage activity, hand held activity were observed. Home cage activities like Body position, Respiration, Clonic involuntary movement, Tonic involuntary movement, Palpebral closure, Approach response, Touch response, Pinna reflex, Sound responses, Tail pinch response were observed. Handheld activities like Reactivity, Handling, Palpebral closure, Lacrimation, Salivation, Piloercetion, Papillary reflex, abdominal tone, Limb tone were observed. Functional and behavioral examination was normal in all treated groups. Food consumption of all treated animals was found normal as compared to normal group.

SUMMARY & CONCLUSION:

Summary:

The present study was conducted to know single dose toxicity of **MILAGU LEGIYAM WITH HONEY/GHEE** on female Wister rats. The study was conducted using 15 female Wister rats. The female animals were selected for study of 8- 12 weeks old with weight range of within ± 20 % of mean body weight at the time of randomization. The groups were numbered as group I, II, III, IV and V and dose with **1000,2000,3000,5000 and 6000mg/kg** of **MILAGU LEGIYAM WITH HONEY/GHEE**. The drug was administered by oral route single time and observed for 14 days. Daily the animals were observed for clinical signs and mortality.

There were no physical and behavioral changes observed in Female Wister rats during 14 days. Mortality was not observed in any treatment groups.

Conclusion:

The study shows that **MILAGU LEGIYAM WITH HONEY/GHEE** did not produce any toxic effect at dose of **1000,2000,3000,5000 and 6000mg/kg** to rats. So No-Observed-Adverse-Effect-Level (NOAEL) of **MILAGU LEGIYAM WITH HONEY/GHEE** is 6000 mg/kg.

7.0 ABBREVIATIONS

No.	Number
Mg	Milligram
Kg	Kilogram
LD_{50}	Lethal Dose $_{50}$
p.o	peros
ML	Milliliter
%	percentage
R&D	Research and Development
g%	Gram percentage
g	Gram
NOAEL	No-Observed-Adverse-Effect-Level
MLD	Minimum Lethal Dose
MTD	Maximum Tolerated Dose

OECD Organisation of Economic Co-operation and Development

CPCSEA Committee for the Purpose of Control and Supervision of Experiments on Animals

8.0 REFERENCES:

1. OECD. Guideline for Testing of Chemicals 423, Acute oral toxicity (acute toxic class method). December 2001.

SUB-ACUTE TOXICITY STUDY IN WISTER RATS TO EVALUATE TOXICITY PROFILE OF MILAGU LEGIYAM WITH HONEY/GHEE

Objective

The objective of this study is to evaluate the toxic effects, if any, as a result of the repeated once daily oral administration of **MILAGU LEGIYAM WITH HONEY/GHEE** to Wister Albino rats for a minimum period of 28 consecutive days. This study will provide information on any major toxic effects, target organs and a rationale for concluding the No-Observed-Adverse-Effect-Level (NOAEL) and/or No Observed Effect Level (NOEL) / LOEL (Low Observed Effect Level) and risk assessment in humans.

1. Test Guidelines

This study plan is prepared as per the following guidelines:

Schedule – Y, Amendment version 2005, Drugs and Cosmetics Rules, 1945.

OECD – 407 – Repeated dose 28-day Oral Toxicity Study in Rodents, Adopted 3 October, 2008.

1.1. Test System Details

Species	:	Rat
Strain	:	Wister Albino
Source	:	Sree Venkateshwara Enterprises Pvt Ltd, Bangalore
Age	:	6-8 weeks
Sex	:	Male / Female (nulliparous and non-pregnant)
Body weight	:	0to 180.0 g 0

1.2. Acclimatization

Animals will be allowed to acclimatize to the experimental room conditions for five days prior to the commencement of dosing. During the acclimatization period, the animals will be observed daily for any apparent adverse clinical signs. Prior to assignment to the study and commencement of treatment, a detailed physical health examination will be performed on all animals by a veterinarian and animals with any evidence of ill health or poor physical condition will not selected for the study.

1.3. Randomization and Grouping

On the starting day of dosing, the animals will be weighed and health examination will be performed by veterinarian. Animals will be randomly allocated to different groups according to their body weight by using MS-Excel sheet as described in the randomization SOP. Animals will be divided into four groups (vehicle control, low, intermediate, and high dose). At the initiation of the treatment, the body weight variation between the groups did not exceed ±20% of the mean weight of each sex.

1.4. Animal Identification

In each cage, animals will be identified with numbers by marking at the base of the ear. The cages will be identified with an attached colored cage label showing study number, study code, group number, sex, dose, strain, species, cage number, route of administration and animal number.

2. Animal Husbandry

2.1. Animal Welfare and approval

The study was approved by the IAEC (SLS) and Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA registration number: Abc14).Their recommendations regarding animal care and handling will be followed.

2.2. Environmental Conditions

The temperature of the experimental room will be maintained at 22±3^{0}C and the relative humidity between 30-70 %. The photoperiod will be 12 hours light and 12 hours dark cycles

2.3. Housing Conditions

Two animals will be housed in autoclaved polypropylene rat cages (Size in mm=L x W x H: 430 x 290 x 160) using paddy husk as the bedding material. Each cage will be fitted with a top grill having provision for keeping rodent pellet feed and an autoclaved polypropylene water bottle with stainless steel drinking nozzle. Cages will be placed on 3-tier racks and cage rotation will be performed every week. Cages will be changed at least twice a week. The cages and water bottles will be cleaned and autoclave sterilized.

2.4. Sanitation

Each day, the floor of the animal room will be swept and mopped. Cages and bedding material will be changed once in three days and water bottles will be changed daily. All the experimental procedures will be done in a clean environment.

2.5. Feed

The experimental animals will be provided with irradiated rodent pellet feed *ad libitum* supplied from Sai feeds Pvt ltd, Chennai . Feed will be withheld for four hours prior to blood collection and necropsy.

2.6. Drinking Water

Animals will be provided with filtered drinking water *ad libitum* passed through water filter system (Aquaguard™) in autoclaved polypropylene bottles. Water bottles will be changed daily. Microbial analysis of water will be carried out once monthly and the report is maintained in the study file.

3. Personnel Safety

All personnel handling animals undergo regular medical examination. Protective clothing like apron, face mask, head cap, and gloves will be used to maintain hygienic conditions.

4. Materials and Methods

4.1. Preparation of Dose formulation

The dose formulation will be prepared under aseptic conditions as per SLS, SOP.

4.2. Route of Administration and Justification

Administration will be by oral gavage, as it is one of the possible routes of exposure.

4.3. Frequency and Duration of Administration

Once daily for 28 consecutive days

4.4. Dosing Procedure

The test item will be administered in once daily by oral gavage using a suitable intubation cannula fitted with a graduated syringe. The scheme of dosing and sacrifice time points are presented in the below below Table.

4.5. Experimental Procedures

All experimental procedures will be performed in accordance with the Study plan and Standard Operating Procedures (SOPs) of SLS.

4.6 DOSAGE SCHEDULE:

The required dose for mice/rat will be calculated by using the standard dose calculation procedure from recommended clinical dose.

CONVERSION FORMULA:

Human dose is 6000 mg /kg day

Total clinical dose (a) x conversion factor (b) 0.018 = (c) per 150 gm of Rat

6000 mg x 2(a) x 0.018 (b) = 108 (c) /150 gm of Rat

108/1000x150 = 16.2 mg

Experimental Doses Calculated as per the standard procedures are

S.No	Groups	Dose /kg, weight	Volume of administration
1	Vehicle Control	--	1 ml
2	Therapeutic Dose	16.2 mg /kg	1 ml
3	Middle Dose	81mg/kg	1 ml
4	High Dose	405mg/kg	1 ml

Experimental Design

Group No.	Group	Dose (mg/kg b.wt /day)	No. of Animals	
			Male	Female
G1	Vehicle control	**HONEY/GHEE**	5	5
G2	Low dose of **MILAGU LEGIYAM WITH HONEY/GHEE**	16.2m g /kg	5	5
G3	Intermediate dose **MILAGU LEGIYAM WITH HONEY/GHEE**	81mg/kg	5	5
G4	High dose **MILAGU LEGIYAM WITH HONEY/GHEE**	405mg/kg	5	5

5. Observations

Animals will be observed daily throughout the treatment period at regular intervals. During the treatment period, animals will be observed twice daily for any clinical signs of toxicity, morbidity and mortality. All the surviving animals will be sacrificed at the end of scheduled period and subjected to gross necropsy and histopathological evaluations.

5.1. Clinical Signs

All the animals will be subjected to cage-side (home-cage) observations twice a day for any clinical signs of toxicity, preferably at the same time each day and considering the peak period of anticipated effect. In addition to home cage observations, a detailed clinical examination will be performed once prior to dosing and weekly thereafter during treatment period.

5.2. Morbidity/ Mortality

All animals will be examined twice a day for mortality and signs of morbidity.

5.3. Body Weights

Body weights will be recorded at the beginning of acclimatization, before randomization, there after at weekly intervals and at the time of necropsy.

5.4. Feed Consumption

Feed consumption will be calculated on a weekly basis throughout the study period.

5.5. Haematology and Clinical Biochemistry

Hematology and clinical biochemistry tests will be performed with terminally collected blood samples on day-29 from all animals. Animals will be deprived of feed overnight and blood samples will be collected by tapping the ear for visibility of the vein site and inserted the needle into the marginal ear vein and collected the blood into micro centrifuge tube. Approximately 0.5 ml of blood will be collected in vials containing 1% EDTA (20µl) as an anticoagulant for hematological analysis.

Approximately 2 ml blood will be collected from each animal in micro centrifuge tubes containing 15µl of heparin (19 units) and the plasma will be separated by centrifugation at 4000 rpm for ten minutes at 4^{o}C. The plasma will be stored at -20 ^{o}C ± 2 and used for all clinical chemistry analysis.

5.6. Hematology

Erythrocyte count (RBC), Total Leucocyte count (WBC), Hemoglobin (Hb), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC) and Platelet (PLTC).

5.7. Clinical Biochemistry

Glucose, Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Alkaline phosphatase (ALP), Total protein, Albumin, Creatinine, Urea, Cholesterol, Triglycerides, Sodium, Potassium, Calcium, and Chloride.

5.8 Pathology

All animals will be euthanized by CO_2 asphyxiation and subjected to necropsy under the supervision of the veterinary pathologist. Different tissues/organs of thoracic, abdominal and cranial cavities will be examined for any gross pathological changes. Tissues from vehicle control and high dose groups will be subjected to detailed histopathological analysis (Ovaries/ testes, kidneys, liver, lungs). The organs will be fixed using Bouin's (reproductive organs) and 10% neutral buffered formalin (kidneys, liver, spleen, lungs).Processing of tissue will be done by spin tissue processer, embedding of the tissue by tissue embedder. The tissues will be initially trimmed to 10-20µ thickness and later 3-6µ to obtain thinner tissue sections by using rotary microtome. Haematoxylin and Eosin staining will be performed for all tissues.

5.8. Organ Weights

Absolute weights of adrenal glands, brain, ovaries/testes, epididymis/uterus, heart, kidneys, liver, spleen and lungs will be recorded for all the animals after trimming adherent tissue immediately after dissection from the animal. Paired organs will be weighed together. Relative weights of these organs against fasting animal body weights will be calculated and reported.

6. Data Compilation

Data will be summarised in a tabular form showing the number of animals, experimental design, dose groups, dose volume and concentrations, test item and vehicle control details. All findings like clinical signs, mortality and morbidity data, time of death, body weights, feed consumption, clinical signs, and necropsy and pathology observations will be recorded and given in the final report. One original copy of the final report is issued to the sponsor.

7. Statistical Analysis

All the parameters of treated groups of both sex, viz. body weight, feed consumption, organ weights (absolute and relative), biochemical parameters, and hematology parameters will be analyzed using SPSS software, version 16.0 by using one-way ANOVA test with multiple comparison (vehicle controls treated groups) in the study report, and p value < 0.05 is considered as statistically significant.

8. References

1. Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guidelines for Laboratory Animal Facility, The Gazette of India, 1998.
2. Hayes AW, 2000. Principles and Methods of Toxicology, 4th ed., Taylor and Francis, London.
3. Karl-Heinz Diehl, R. H. (2001). A Good Practice Guide to the Administration of Substances and Removal of Blood, Including Routes and Volumes. journal of applied toxicology , 15-23.
4. OECD – 407 - Repeated dose 28-day oral Toxicity Study in Rodents, Adopted October 3, 2008.
5. Schedule – Y, Amendment version 2005, Drugs and Cosmetics Rules, 1945.

MATERIALS AND METHODS

ESTIMATION OF HEMATOLOGICAL PARAMETERS: [1]

Collection of blood for hematological studies

After the treatment period the animals were anaesthetized by ketamine hydrochloride and the blood was collected from Retro-orbital sinus by using capillary into a centrifugation tube which contains EDTA for haematological parameters The haematological parameters like RBC, WBC and Hb percentage, Differential cell count, MCV, MCHC, Hematocrit, MCH, platelet count were estimated by the following procedures.

1. ENUMERATION OF RED BLOOD CELLS: [1] Ramnic 2007)

Reagents : RBC diluting fluid

Procedure:

Using a red blood cell pipette of haemocytometer, well mixed blood was drawn up to 0.5 mark and RBC diluting fluid was taken up to mark II. The fluid blood mixture was shaken and transferred onto the counting chamber. The cells were

allowed to settle to the bottom of the chamber for 2 min. See the fluid does not get dried. Using 45X or high power objective the RBC's were counted uniformly in the larger corner squares.

The cells were expressed as number of cells $x10^{12}$/l

2. ENUMERATION OF WBC: [2] John 1972)

Reagents:

Turk's fluid: Turk's fluid was prepared by mixing 2ml of acetic acid with 100 ml of distilled water. To this 10 drop of aqueous methylene blue 3 % w/v) was added. This solution haemolysis the red cells due to acidity so that counting of white cells becomes easy.

Procedure:

Using a white blood cell pipette of haemocytometer, well mixed blood was drawn up to 0.5 mark and WBC diluting fluid was taken up to mark II. The fluid blood mixture was shaken and transferred onto the counting chamber. The cells were allowed to settle to the bottom of the chamber for 2 min. See the fluid does not get dried.

Using 10X or low power objective the WBC's were counted uniformly in the larger corner squares.

The cells were expressed as number of cells/10mm.

3. DIFFERENTIAL LEUCOCYTE COUNT: [3] John 1972)

Reagent:

Leishmann's stain: 150mg of powdered leishmann's stain was dissolved in 133ml of acetone free methanol.

Procedure:

A blood film stained with leishmann's stain was examined under oil immersion and the different types of WBCs were identified. The percentage distribution of these cells was then determined. Smears were made from anticoagulant blood specimens and stained with leishmann's stain. The slides were preserved for counting the number of lymphocytes and neutrophils, per 100 cells were noted.

From the different Leukocyte count and WBC count, absolute lymphocyte and neutrophil count were calculated.

$$\text{Absolute neutrophil count} = \frac{\text{Number of neutrophils}}{100} \times \text{TWBC}$$

$$\text{Absolute lymphocyte count} = \frac{\text{Number of lymphocytes}}{100} \times \text{TWBC}$$

DETERMINATION OF BIOCHEMICAL PARAMETERS:

For assessment of biochemical parameters, blood samples were collected from the animals by puncturing the retro-orbital plexus and centrifuged. The serum collected after centrifugation was analyzed for various biochemical parameters like SGOT, SGPT, ALP,TC.TG,HDL All of the above biochemical parameters were estimated using semi autoanalyzer (Photometer 5010 $_{V5+}$, Germany) with enzymatic kits procured from Piramal Healthcare limited, Lab Diagnostic Division, Mumbai, India.

1. Total Cholesterol (TC)

Principle

Determination of cholesterol is done after enzymatic hydrolysis and oxidation. The colorimetric indicator is quinoneimine, which is generated from 4-aminoantipyrine and phenol by hydrogen peroxide under the catalytic action of peroxidase (trinder's reaction).

$$\text{Cholesterol ester} + H_2O \xrightarrow{CHE} \text{Cholesterol} + \text{Fatty acid}$$

$$\text{Cholesterol} + O_2 \xrightarrow{CHO} \text{Cholesterol-3-one} + H_2O_2$$

$$2H_2O_2 + \text{4- Amino antipyrine} + \text{Phenol} \xrightarrow{POD} \text{Quinonelimine} + 4\ H_2O_2$$

Method

CHOD-PAP: Enzymatic photometric test

Table 6: Reagents

Goods buffer (pH 6.7)	50 mmol/ l
Phenol	5 mmol/l
4-aminoantipyrine	0.3 mmol/l
Cholesterol estrase	> 200 U/l
Cholesterol oxidase	> 100 U/l
Peroxidase	3 KU/l
Standard	(5.2 mmol/l)

Assay procedure

a. 1 ml (1000 µl) of reagent-1 is taken in a 5 ml test tube.
b. Added 0.01 ml (10 µl) of serum.
c. Mixed well and incubated at 37°C for 5 min.
d. Read the test sample.

NORMAL RANGE: < 200 mg/dl in serum.

1. Deeg R, Ziegenhorn J, Kinetic enzymatic method for automated determination of total cholesterol in serum, Clin. Chem., 1983, 29:1798-802.

2. Triglycerides

Principle

Determination of triglycerides (TG) alters enzymatic splitting with lipoprotein lipase. Indicator is quinoneimine which is generated from 4-aminoantipyrine and 4-chlorophenol by hydrogen peroxidase under the catalytic action of peroxidase.

$$\text{Triglycerides} \xrightarrow{\text{LPL}} \text{Glycerol + fatty acid}$$

$$\text{Glycerol + ATP} \xrightarrow{\text{GK}} \text{Glycerol-3-phosphate+ ADP}$$

$$\text{Glycerol-3-phosphate} + O_2 \xrightarrow{\text{GPO}} \text{Dihydroxyaceton phosphate} + H_2O_2$$

$$2H_2O_2 + \text{4- Amino antipyrine + 4- chlorophenol} \xrightarrow{\text{POD}} \text{Quinonelimine + HCL +} \; 4H_2O_2$$

Method

Colorimetric enzymatic test using glycerol-3-phosphate-oxidase (GPO).

Reagents

Components and concentrations in the test Goods buffer pH 7.2, 50 mmol/ l

Table 7: Reagents

4-chloroPhenol	4 mmol/l
ATP	2 mmol/l
Mg^{2+}	15 mmol/l
Glycerokinase	> 0.4 Kµ/l
Peroxidase	> 2 Kµ/l
Lipoprotein lipase	> 4 Kµ/l
4-aminoantipyrine	0.5 mmol/l
Glcerol-3-phosphate- oxidase	> 1.5Kµ/l
Standard	(2.3 mmol/l)

Assay procedure

a. 1 ml (1000 µl) of reagent-1 is taken in a 5 ml test tube.
b. Added 0.01 ml (10 µl) of serum.
c. Mixed well and incubated at 37°C for 15 min.
d. Read the test sample.

Normal Range: < 200 mg/dl in serum.

1. Cole T.G, Klotzsch S.G, Mcnarmara J, Measurement of triglyceride concentration, In Rifai N, Warnick G.R, Dominiczak M.H, Handbook of lipoprotein testing, Washington:AACC, Press, 1997, 115-26.

3. HDL Cholestrol

Principle

Chylomicrons, VLDL and LDL are precipitated by adding phosphotungstic acid and magnesium ions to the sample. Centrifugation leaves only the HDL in the supernatant. The cholesterol content in it is determined enzymatically.

Method

Phosphotungstic acid precipitation method.

Table 8: Reagents

Phosphotungstic acid	0.55 mmol/l
Magnesium chloride	25 mmol/l

Assay procedure

A. Preparation of supernatant for the HDL-CHL estimation

Added 200 µl of serum to the 500 µl of HDL-Cholesterol precipitating reagent (from HDL kit) in 1.5 ml centrifuge tube and mixed well. Centrifuged the above solution at 4000 rpm for 10 min.

B. Preparation of test sample for the estimation of HDL-Cholesterol

a. Taken 1000 µl of reagent-1 (from cholesterol kit) in a 5 ml test tube.
b. Added, 100 µl of supernatant from above centrifuged solution
c. Mixed well and incubated at 37°C for 15 min.
d. Read the test sample.

Normal Range: > 60 mg/dl in serum.

1. Friedewald W.T, Levy R.T, Frederickson D.S, Estimation of VLDL and LDL cholesterol, Clin. Chem., 1972, 18:499-502.

4. ESTIMATION OF SERUM GLUTAMATE PYRUVATE TRANSAMINASES (SGPT/ ALT)

1. Determination of aspartate aminotransferase (AST)

Aspartate aminotransferase, also known as Glutamate Oxaloacetate Transaminase (GOT) catalyses the transamination of L-aspartate and α keto glutarate to form oxaloacetate and L- glutamate. Oxaloacetate formed is coupled with 2,4-Dinitrophenyl hydrazine to form hydrazone, a brown coloured complex in alkaline medium which can be measured colorimetrically.

Reagents

Buffered aspartate (pH 7.4); 2,4- DNPH reagent; 4N sodium hydroxide; working pyruvate standard; solution I (prepared by diluting 1 ml of reagent 3 to 10 ml with purified water).

Procedure

Rietman and Frankle method was adopted for the estimation of SGOT. (Reitmann S, Frankel S, 1957. A colorimetric method for the determination of serum oxaloacetic and glutamic pyruvate transminases. American Journal of Clinical Pathology.28: 56-63.The reaction systems used for this study included blank, standard, test (for each serum sample) and control (for each serum sample). 0.25 ml of buffered aspartate was added into all the test tubes. Then 0.05 ml of serum was added to the test group tubes and 0.05 ml of working pyruvate standard into the standard tubes. After proper mixing, all the tubes were kept for incubation at 37^{o}C for 60 min, after which 0.25 ml each of 2,4- DNPH reagent was added into all the tubes. Then, 0.05 ml of distilled water and 0.05 ml of each serum sample was added to the blank and the serum control tubes respectively. The mixture was allowed to stand at room temperature for 20 min. After incubation, 2.5 ml of solution I was added to all test tubes. Mixed properly and optical density was measured in a spectrophotometer at 505 nm within 15 min.

The enzyme activity was calculated as:-

AST (GOT) activity in IU/L) = [(Absorbance of test **-** Absorbance of control)/ (Absorbance of standard - Absorbance of blank)] x concentration of the standard

2. Determination of alanine aminotransferase (ALT)

Alanine aminotransferase, also known as Glutathione Peroxidase (GPT) catalyses the transamination of L-alanine and α keto glutarate to form pyruvate and L-Glutamate. Pyruvate so formed is coupled with 2,4 – Dinitrophenyl hydrazine to form a corresponding hydrazone, a brown coloured complex in alkaline medium which can be measured colorimetrically.

Reagents

Buffered alanine (pH 7.4), 2,4–DNPH, 4N sodium hydroxide, working pyruvate standard, solution I (prepared by diluting 1 ml of reagent 3 to 10 ml with purified water).

Procedure

Rietman and Frankle method was dopted for the estimation of SGPT. The reaction systems used for this study included blank, standard, test (for each serum sample) and control (for each serum sample). 0.25 ml of buffered alanine was added into all the test tubes. This was followed by the addition of 0.05 ml of serum into the test group tubes and 0.05 ml of working pyruvate standard into the standard tubes. After proper mixing, all the tubes were kept for incubation at 37^{o}C for 60 minutes, after which 0.25 ml each of 2,4- DNPH reagent was added into all the tubes. Then, 0.05 ml of distilled water and 0.05 ml of each serum sample was added to the blank and the serum control tubes respectively. The mixture was allowed to stand at room temperature for 20 min. After incubation, 2.5 ml of solution **I** was added to all test tubes. Mixed properly and optical density was read against purified water in a spectrophotometer at 505 nm within 15 min.

The enzyme activity was calculated as:- ALT (GPT) activity in IU/L) = [(Absorbance of test **-** Absorbance of control)/ (Absorbance of standard - Absorbance of blank)] x concentration of the standard.

3. Determination of alkaline phosphatase (ALP)

Alkaline phoshatase from serum converts phenyl phosphate to inorganic phosphate and phenol at pH 10.0. Phenol so formed reacts in alkaline medium with 4-aminoantipyrine in presence of the oxidising agent potassium ferricyanide and forms an orange-red coloured complex, which can be measured spectrometrically. The color intensity is proportional to the enzyme activity.

Reagents:

Buffered substrate

Chromogen Reagent

Phenol Standard, 10 mg%

Procedure:

ALP was determined using the method of Kind (Kind PRM, King EJ, 1972. *In-vitro* determination of serum alkaline phosphatase. Journal of Clinical Pathology 7: 321-22\). The working solution was prepared by reconstituting one vial of buffered substrate with 2.2 ml of water. 0.5 ml of working buffered substrate and 1.5 ml of purified water was dispensed to blank, standard, control and test. Mixed well and incubated at 37^0C for 3 min. 0.05 ml each of serum and phenol standard were added to test and standard test tubes respectively. Mixed well and incubated for 15 min at 37^0C. Thereafter, 1 ml of chromogen reagent was added to all the test tubes. Then, added 0.05 ml of serum to control. Mixed well after addition of each reagent and the O.D of blank, standard, control and test were read against purified water at 510 nm. Serum alkaline phosphatase activity in KA units was calculated as follows

[(O.D. Test-O.D. Control) / (O.D. Standard- O.D. Blank)] x 10

4. Determination of bilirubin

In toxic liver, bilirubin levels are elevated. Hyperbilirubinemia can result from impaired hepatic uptake of unconjugated bilirubin, such a situation can occur in generalized liver cell injury, certain drugs (e.g Rifampin and probenecid) interfere with the rat uptake of bilirubin by the liver cell and may produce a mild unconjugated hyperbilirubinemia. Bilirubin level rises in diseases of hepatocytes, obstruction to bilirubin excretion into duodenum, in haemolysis and defects of hepatic uptake and conjugation of Bilirubin pigment such as Gilbert's disease.

Elevation of total serum bilirubin may occur due to:

1. 1.Excessive haemolysis or destruction of the red blood cells.Eg:Haemolytic disease of the new born.
2. 2.Liver diseases.Eg.Hepatitis and cirrhosis.
3. 3.Obstruction of the biliary tract.Eg.Gall stones.

The method is based on the reaction of Sulfonilic acid with sodium nitrite to form azobilirubin which has maximum absorbance at 546nm in the aqueous solution.

The intensity of the color Produced is directly proportional to the amount of direct or total bilurubin concentration present in the sample.

Reagents

1. Diazo A-(Reagent-R1) :Ready to use
2. Diazo B-(Reagent-R2):Ready to use
3. Bilirubin Activater :Ready to use

Procedure

Kind & King's method was followed for the estimation of Bilirubin. Five hundred µl of working reagent was added to 50 µl of rat serum & incubated for 5 min at 37°C. Absorbance was measured AT 546 NM in semi auto analyzer against the standard.

The Bilirubin content was calculated using the following equation:

Total bilirubin (mg/dt) = Abs of the sample blank x 15.

Direct Bilirubin(mg/dt) = Abs of sample blank x 10.

5. ESTIMATION OF UREA

Urea is the nitrogen-containing end product of protein catabolism. States associated with elevated levels of urea in blood are referred to as hyper uremia or azotemia.

Method

Estimation of urea was done by Urease-GLDH: enzymatic UV test.

Principle

$$\text{Urea} + 2H_2O \xrightarrow{\text{Urease}} 2NH_4 + 2HCO_3$$

$$\text{2- Oxoglutarate} + NH_4^+ + \text{NADH} \xrightarrow{\text{GLDH}} \text{L- Glutamate} + NAD^+ + H_2O$$

Table 14. Reagents

R 1	TRIS pH 7.8	120 mmol/l
	2-Oxoglutarate	7 mmol/l
	ADP	0.6 mmol/l
	Urease	≥ 6 KU/l
	GLDH	≥ 1 KU/l
R 2	NADH	0.25 mmol
R 3	Standard	40 mg/dl

Procedure

a. Take 1000 µl of reagent-1 and 250 µl of reagent-2 in 5 ml test tube.
b. To this, add 10 µl of serum.
c. Mix well and immediately read the test sample at 340 nm Hg 334 nm Hg 365 nm optical path 1 cm against reagent blank (2-point kinetic).
d. And note down the value.

Normal range: 10 – 50 mg/dl.

6. ESTIMATION OF URIC ACID

Uric acid and its salts are end products of the purine metabolism. In gout the most common complication of hyperuricemia, ie. Increased serum levels of uric acid lead to formation of monosodium urate crystal around the joints.

Method

Enzymatic photometric test using TOOS (N ethyl- N (hydroxyl -3-sulfopropyl)-m- toluidin)

Principle

Uric acid + H_2O + O_2 $\xrightarrow{\text{uricase}}$ Allantoin +CO_2 +H_2O_2

TOOS + 4 aminoantipyrine + $2H_2O_2$ $\xrightarrow{\text{POD}}$ Indamine + $3H_2O$

Table 15.reagents

R1	Phosphate buffer pH 7.0	100mmol/l
	TOOS	1mmol/l
	Ascorbate oxidase	≥1 KU/l
R2	Phosphate buffer pH 7.0	100mmol/l
	4- amino antipyrine	0.3mmol/l
	K_4 (Fe(CN)$_6$)	10µmol/l
	Peroxidase	≥1KU/l
	Uricase	≥50U/l

Procedure

a. Take 800µl of reagents -1 in a2ml centrifuge tube.
b. To this add 20µl of serum.
c. Mix well and incubate at 30°c for 5 minutes.
d. Then add 200µl of reagent2

e. Mix well incubate for 5min at 37°c

f. Measure the not down the values.

Normal range: 1.9-8.2mg/dl

7. ESTIMATION OF CREATININE:

Principle:

Creatinine forms a coloured complex with picrate in alkaline medium.

The rate of formation of the complex is measured.

Reagents:

Reagent 1 Standard Creatinine (2mg/100ml)

Reagent 2 Picric acid solution.

Reagent 3 sodium hydroxide solution

Procedure:

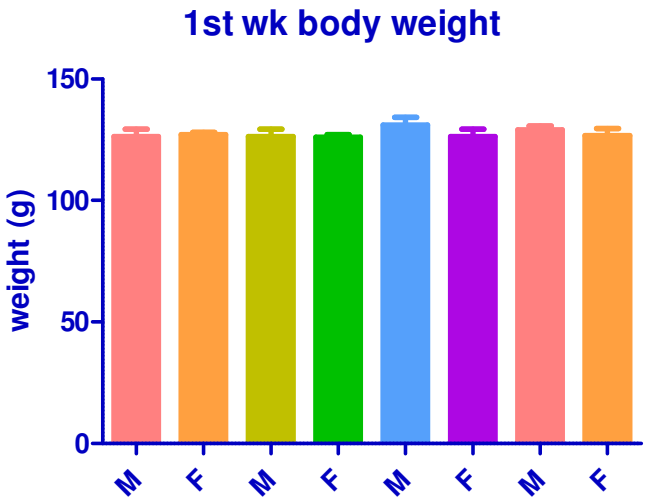
Take 500 µl of reagent -2 and 500 µl of reagent -3 in a 5ml test tube. To this add 100 µl of serum. Mix well and immediately read the test sample at Hg 492 nm 1cm light path and note down the values.

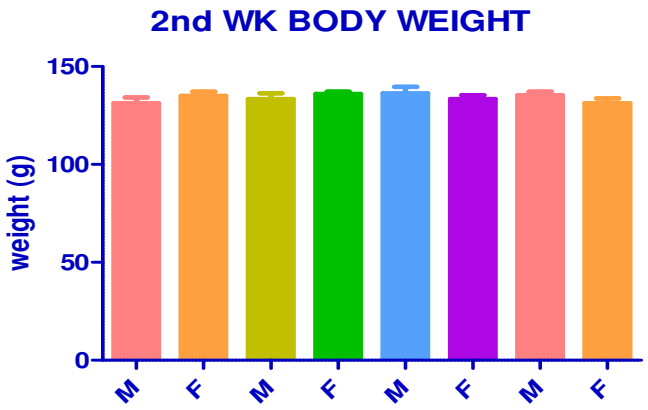
Normal range is 0.6 -1.1 mg/dl.

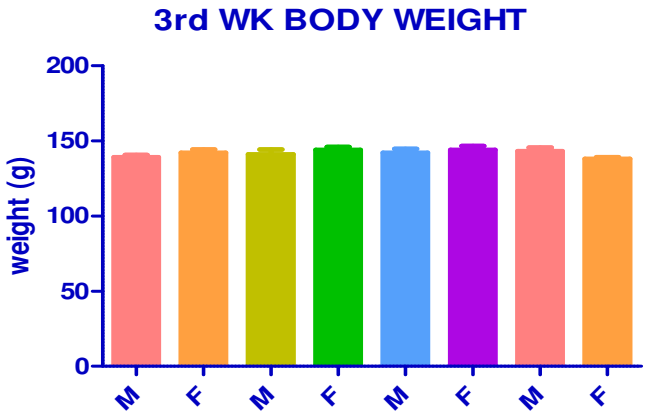
TABLE: 1 EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF MILAGU LEGIYAM WITH HONEY/GHEE ON BODY WEIGHT IN Gram (PHYSICAL PARAMETER)

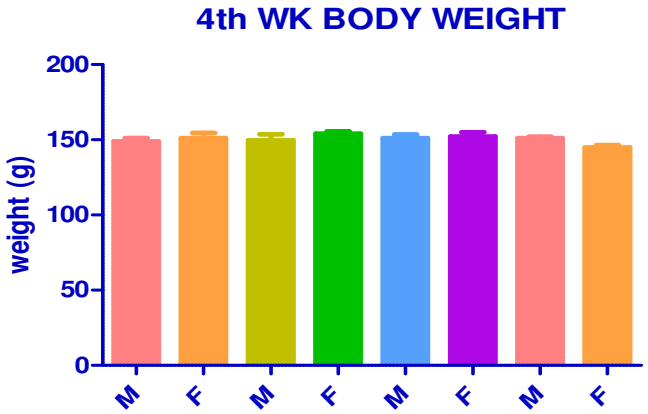
GPs	Control		Low Dose		Middle Dose		High Dose	
	Male	Female	Male	Female	Male	Female	Male	Female
1st wk	126.3±2.963	127±1	126.3±2.963	126±1.155	131±3.215	126.3±2.963	129±1.732	126.7±2.906
2nd wk	131.3±2.848	135±2.082	133.3±2.963	136±1.155	136.3±3.18	133.3±2.028	135.3±1.764	131.3±2.404
3rd wk	139±1.732	142±2.309	141±3.215	144±2	142.3±2.404	144±2.646	143.3±2.186	138±1.155
4th wk	149±2.309	151.3±3.283	149.7±4.055	154±1.528	151±2.517	152.3±2.728	151±1.155	145±1.528

Values are expressed as the mean ± S.D




2nd WK BODY WEIGHT
weight (g)
150
100
50
0
M
F
M
F
M
F
M
F


3rd WK BODY WEIGHT
weight (g)
200
150
100
50
0
M
F
M
F
M
F
M
F

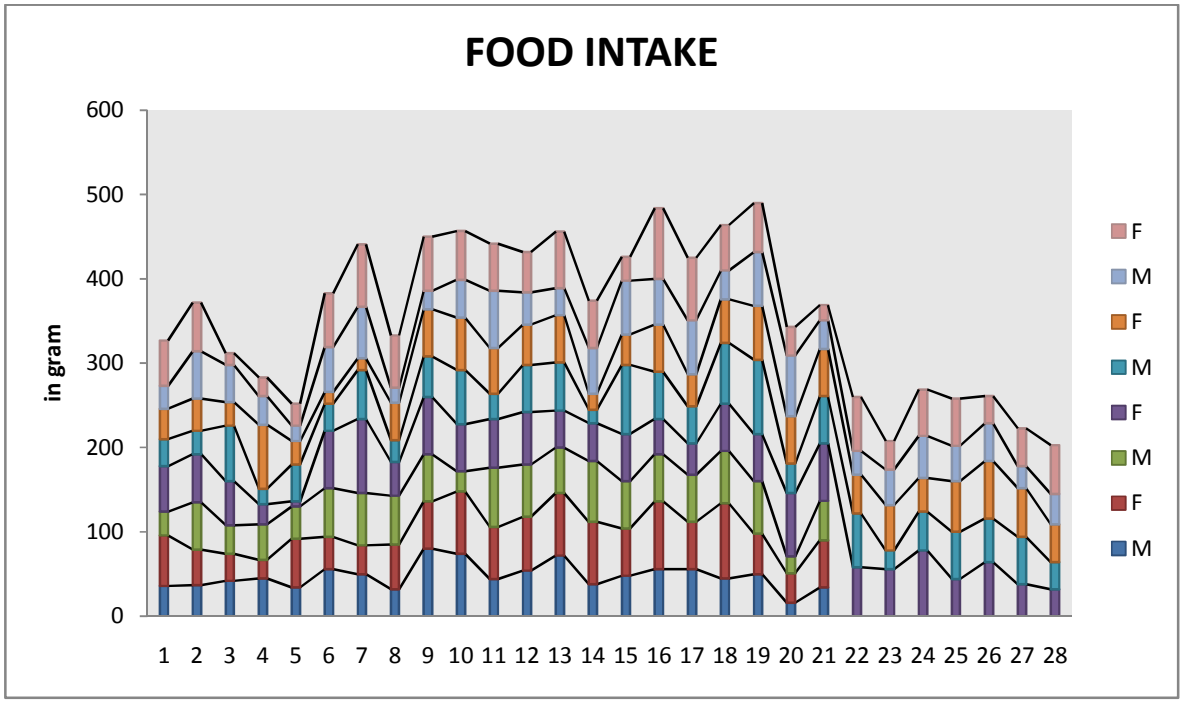

4th WK BODY WEIGHT
weight (g)
200
150
100
50
0
M
F
M
F
M
F
M
F

EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF MILAGU LEGIYAM WITH HONEY/GHEE ON FOOD INTAKE In Gram

Groups	Control		Low Dose		Middle Dose		High Dose	
DAY	Male	Female	Male	Female	Male	Female	Male	Female
Day 1	36	60	28	54	32	36	27	54
DAY2	37	42	56	57	28	38	56	58
DAY3	42	32	34	52	66	28	44	14
Day 4	45	22	42	24	18	76	34	22
DAY5	34	58	38	6	44	28	18	26
Day 6	56	38	58	68	32	14	53	64
DAY7	50	34	62	88	58	14	61	74
DAY8	32	53	58	40	26	44	18	62
Day 9	80	56	56	68	48	56	22	64
DAY10	74	74	24	56	64	62	45	58
Day 11	44	62	70	58	30	54	68	56
DAY12	54	64	62	62	56	48	38	48
DAY13	72	74	54	44	57	56	32	67
Day 14	38	74	72	45	16	19	54	56
DAY15	48	56	56	56	82	36	64	28
Day 16	56	80	56	42	56	56	54	84
DAY17	56	56	56	37	44	38	64	74
DAY18	45	89	62	56	72	52	34	54
Day 19	50	48	62	56	88	64	64	58

DAY20	16	35	20	75	35	56	72	34
DAY21	34	56	47	68	56	56	34	18
Day 22	64	45	62	58	64	46	28	64
DAY23	78	56	42	56	22	54	42	34
DAY24	58	18	34	78	46	40	50	55
Day 25	64	30	68	44	56	60	42	56
DAY26	80	34	64	64	52	68	45	32
DAY27	46	58	56	38	56	58	26	45
DAY28	68	56	58	32	32	45	36	58

Values are expressed as the mean ± S.D

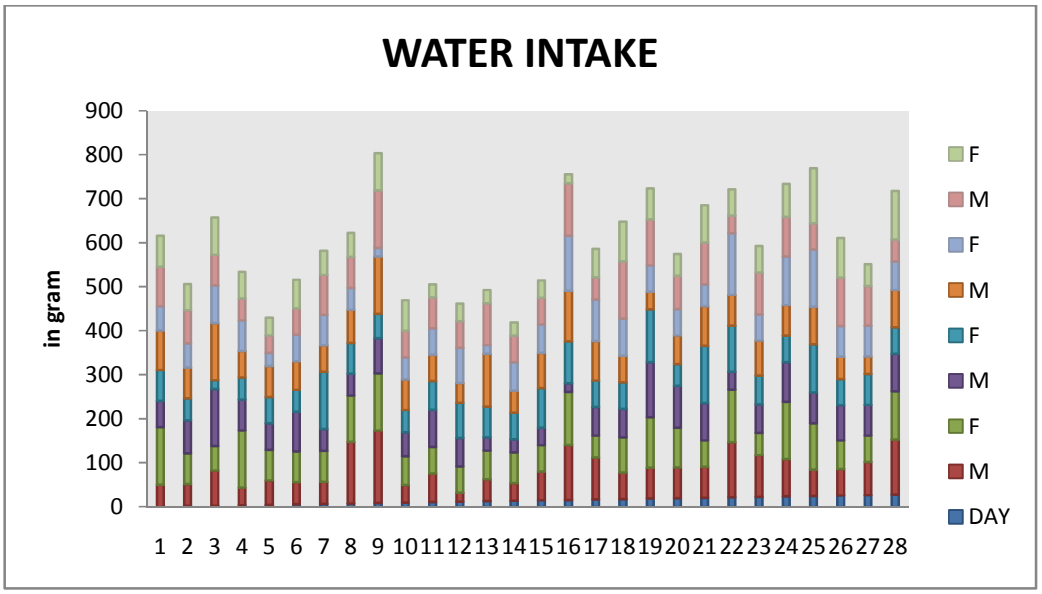


EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF MILAGU LEGIYAM WITH HONEY/GHEE ON WATER INTAKE IN ml

Groups	Control		Low Dose		Middle Dose		High Dose	
DAY	Male	Female	Male	Female	Male	Female	Male	Female
Day 1	50	130	60	70	90	55	90	70
DAY2	50	70	75	50	70	55	75	60
DAY3	80	55	130	20	130	85	70	85
Day 4	40	130	70	50	60	70	50	60
DAY5	55	70	60	60	70	30	40	40
Day 6	50	70	90	50	65	60	60	65
DAY7	50	70	50	130	60	70	90	55
DAY8	140	105	50	70	75	50	70	55
Day 9	165	130	80	55	130	20	130	85
DAY10	40	65	55	50	70	50	60	70
Day 11	65	60	85	65	60	60	70	30
DAY12	20	60	65	80	45	80	60	40
DAY13	50	65	30	70	120	20	95	30
Day 14	40	70	30	60	50	65	60	30
DAY15	65	60	40	90	80	65	60	40
Day 16	125	120	20	95	115	125	120	20
DAY17	95	50	65	60	90	95	50	65
DAY18	60	80	65	60	60	85	130	90
Day 19	70	115	125	120	40	60	105	70
DAY20	70	90	95	50	65	60	75	50

DAY21	70	60	85	130	90	50	95	85
Day 22	125	120	40	105	70	140	40	60
DAY23	95	50	65	65	80	60	95	60
DAY24	85	130	90	60	70	110	90	75
Day 25	60	105	70	110	85	130	60	125
DAY26	60	65	80	60	50	70	110	90
DAY27	75	60	70	70	40	70	90	50
DAY28	125	110	85	60	85	65	50	110

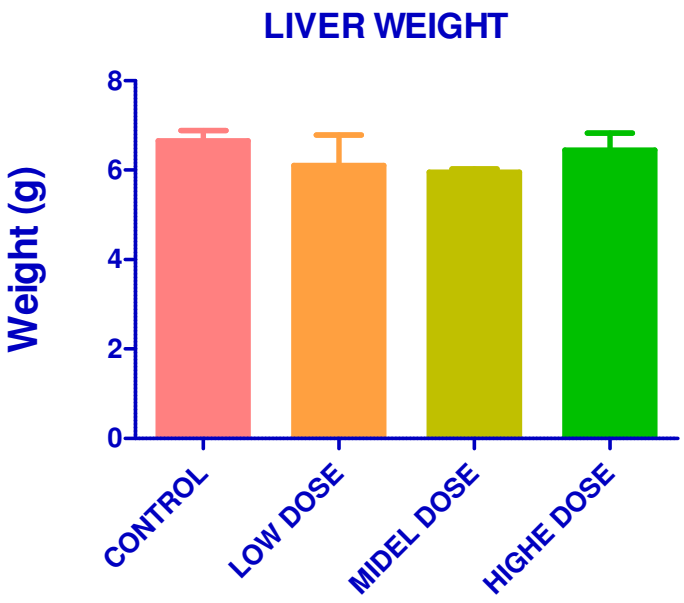
Values are expressed as the mean ± S.D

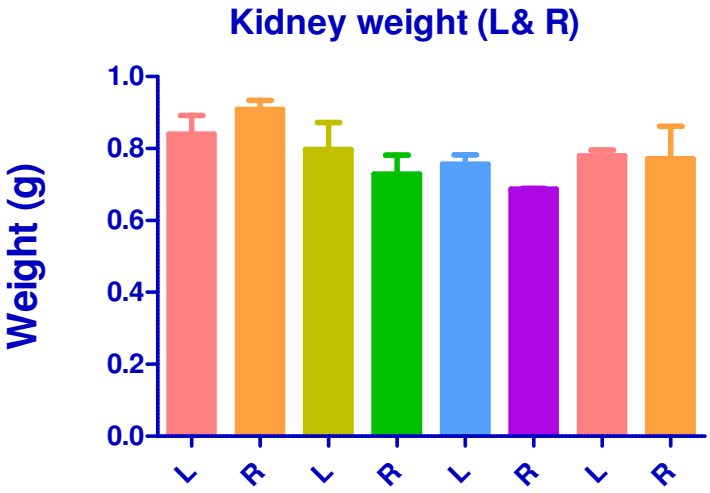


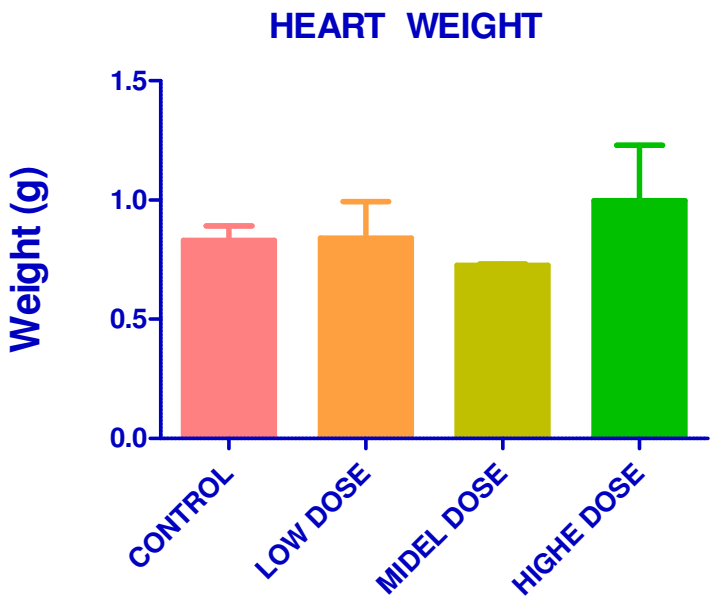
EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF MILAGU LEGIYAM WITH HONEY/GHEE ON ORGAN WEIGHT in gm

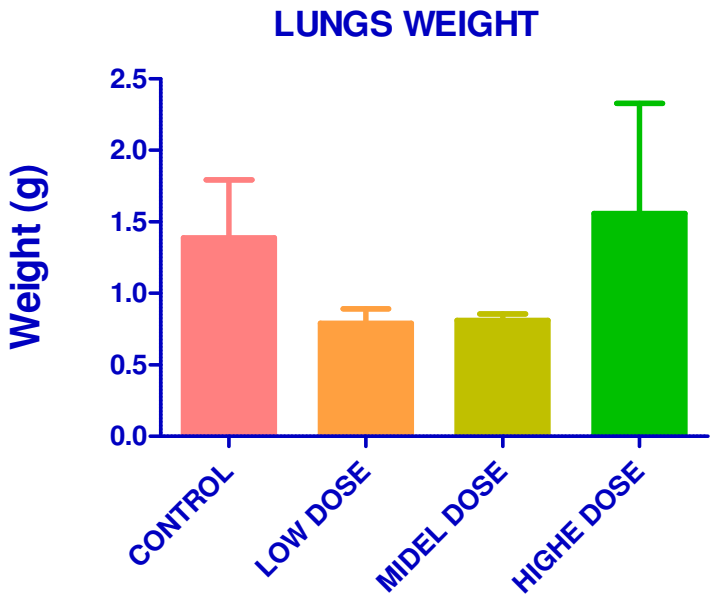
GROUP		**CONTROL**	**Low Dose**	**Middle Dose**	**High Dose**
LIVER WEIGHT		6.659±0.231	6.103±0.679	5.954±0.0775	6.449±0.383
KIDNEY WEIGHT	L	0.8405±0.0515	0.798±0.075	0.7575±0.0255	0.7805±0.0155
	R	0.909±0.025	0.7295±0.0525	0.687±0.002	0.772±0.09
HEART WEIGHT		0.83±0.062	0.841±0.152	0.7265±0.0055	0.997±0.232
LUNGS WEIGHT		1.388±0.4045	0.791±0.102	0.812±0.044	1.559±0.7695
TESTIS WEIGH		2.593±0.505	2.903±0.121	1.888±0.46	2.005±0.0225
UTERUS		0.4905±0.0315	0.4215±0.0335	0.4375±0.0855	0.514±0.188

Values arae expressed as mean ± SEM Statistical significance (p) calculated by one way ANOVA followed by dunnett's (n=6); $^{ns}p>0.05$, *$p<0.05$, **$p<0.01$, ***$p<0.001$, calculated by comparing treated groups with control group.

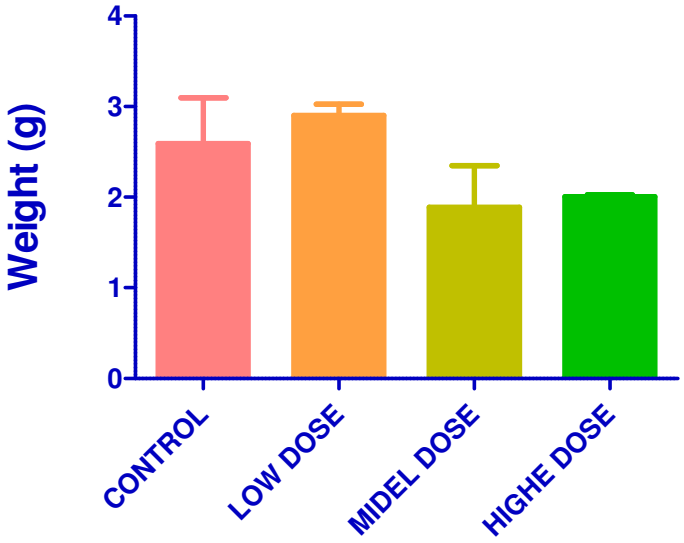

LIVER WEIGHT
Weight (g)
8
6
4
2
0
CONTROL
LOW DOSE
MIDEL DOSE
HIGHE DOSE


Kidney weight (L& R)
Weight (g)
1.0
0.8
0.6
0.4
0.2
0.0
L
R
L
R
L
R
L
R

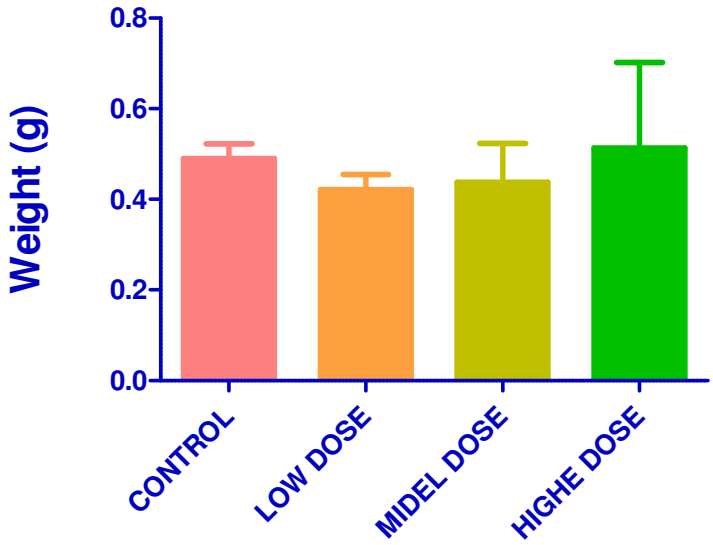

HEART WEIGHT
Weight (g)
1.5
1.0
0.5
0.0
CONTROL
LOW DOSE
MIDEL DOSE
HIGHE DOSE


LUNGS WEIGHT
Weight (g)
2.5
2.0
1.5
1.0
0.5
0.0
CONTROL
LOW DOSE
MIDEL DOSE
HIGHE DOSE

TESTIS WEIGHT



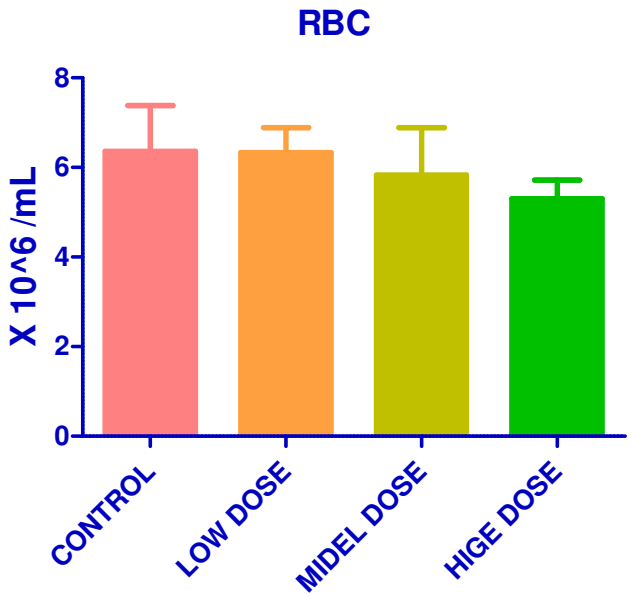
UTERUS

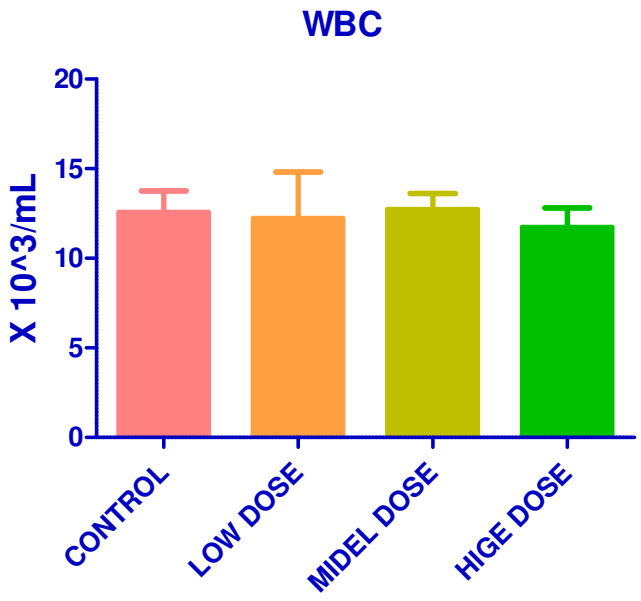


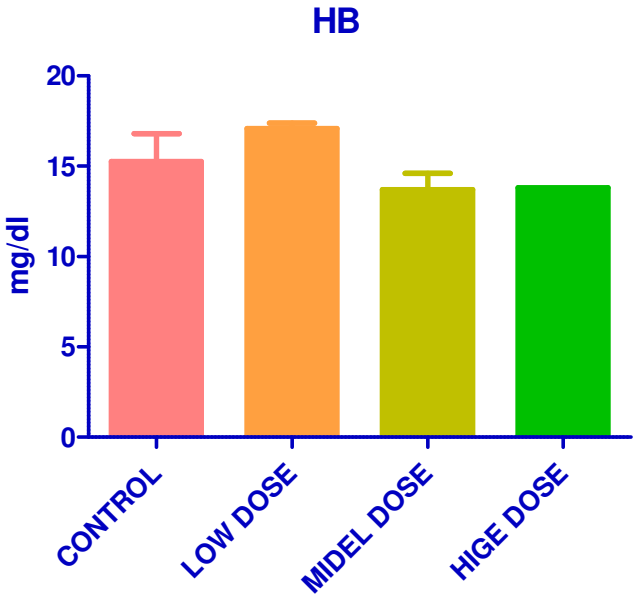
EFFECT OF SUB ACUTE DOSES (28 DAY) 0F MILAGU LEGIYAM WITH HONEY/GHEE ON HAEMATOLOGICAL PARAMETERS

Groups	Control	Low Dose	Middle Dose	High Dose
Rbc ($X10^6$/µl)	6.36±1.02	6.335±0.555	5.835±1.055	5.305±0.415
Wbc($X10^3$/µl)	12.55±1.21	12.2±2.6	12.7±0.9	11.7±1.1
Hb (g/dl)	15.25±1.55	17.1±0.3	13.7±0.9	13.8±0

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.



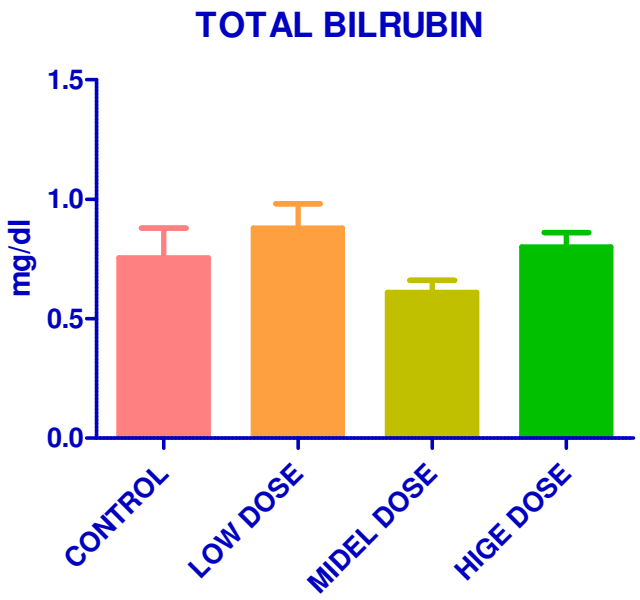

WBC
X 10^3/mL
20
15
10
5
0
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE


HB
mg/dl
20
15
10
5
0
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE

EFFECT OF SUB ACUTE DOSES (28 DAY) 0F MILAGU LEGIYAM WITH HONEY/GHEE ON BIOCHEMICAL PARAMETER (LIVER PROFILE)

Groups	Control	Low Dose	Middle Dose	High Dose
Total Bilirubin(mg/dl)	0.755±0.125	0.88±0.1	0.61±0.05	0.8±0.06

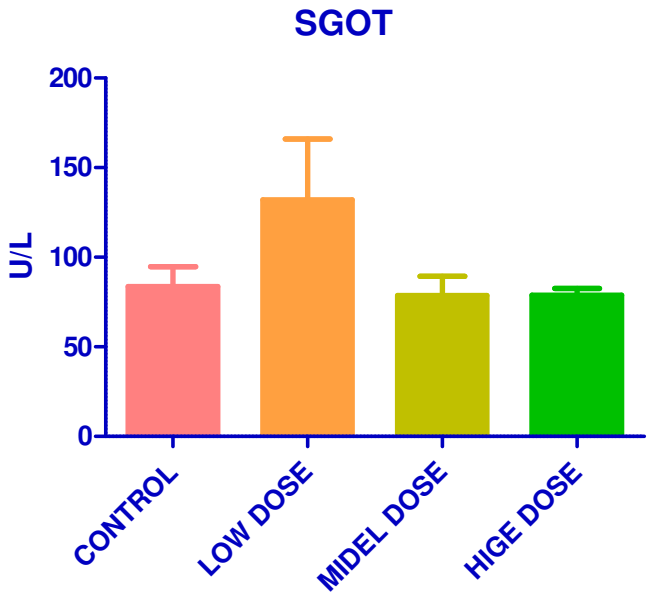
Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.

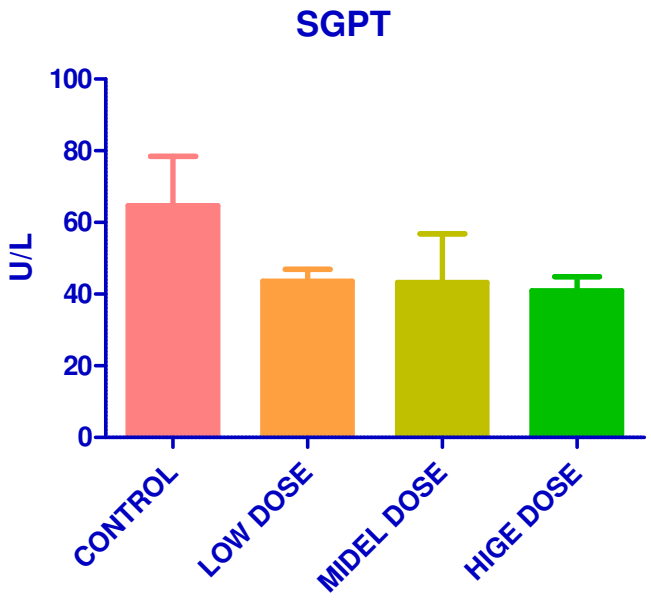


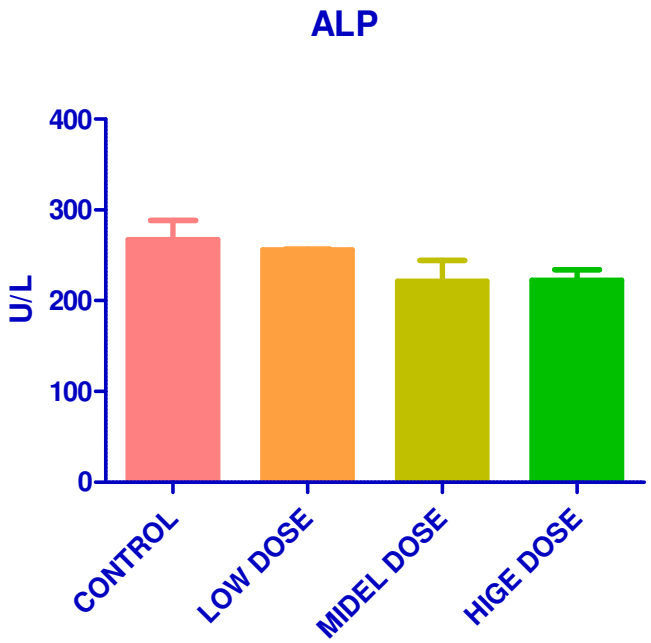
EFFECT OF SUB ACUTE DOSES (28 DAY) 0F MILAGU LEGIYAM WITH HONEY/GHEE ON BIOCHEMICAL PARAMETER (LIVER PROFILE)

Groups	Control	Low Dose	Middle Dose	High Dose
SGOT (U/L)	83.7±11.1	132.2±33.85	78.6±10.8	78.9±3.7
SGPT (U/L)	64.65±13.75	43.55±3.35	43.2±13.6	40.85±3.95
ALP (U/L)	267.1±21.45	256.1±0.85	221.6±23	222.5±11.5

Values are expressed as the mean ± S.D; Statistical significance (p) calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.



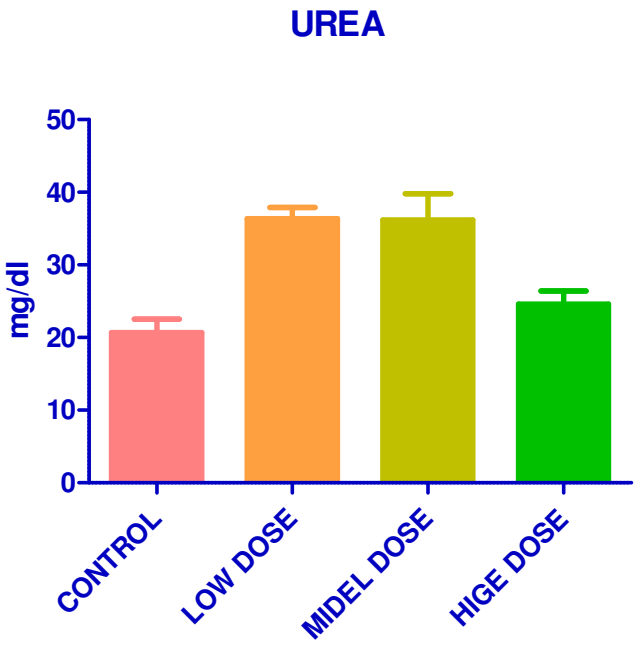

SGPT
100
80
60
40
20
0
U/L
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE


ALP
400
300
200
100
0
U/L
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE

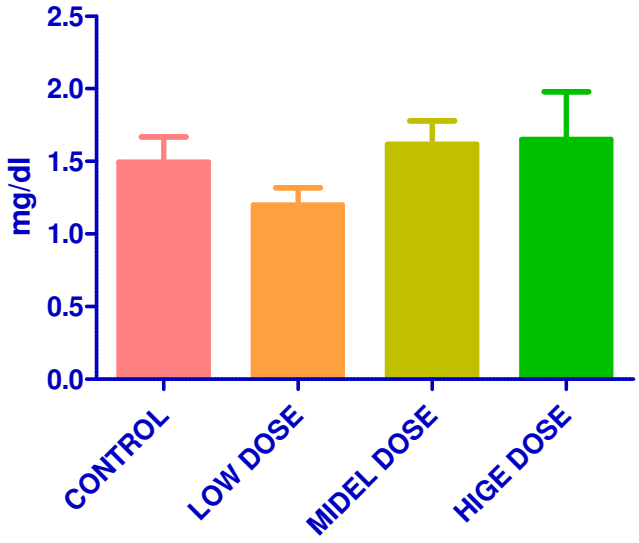
EFFECT OF SUB ACUTE DOSES (28 DAY) 0F MILAGU LEGIYAM WITH HONEY/GHEE ON BIOCHEMICAL PARAMETER (KIDNEY PROFILE)

Groups	Control	Low Dose	Middle Dose	High Dose
Urea (mg/dl)	20.7±1.8	36.35±1.55	36.2±3.6	24.6±1.8
Uric acid (mg/dl)	1.495±0.175	1.2±0.12	1.62±0.16	1.65±0.33
Creatinin (mg/dl)	0.19±0.03	0.385±0.045	0.3±0.02	0.24±0.02

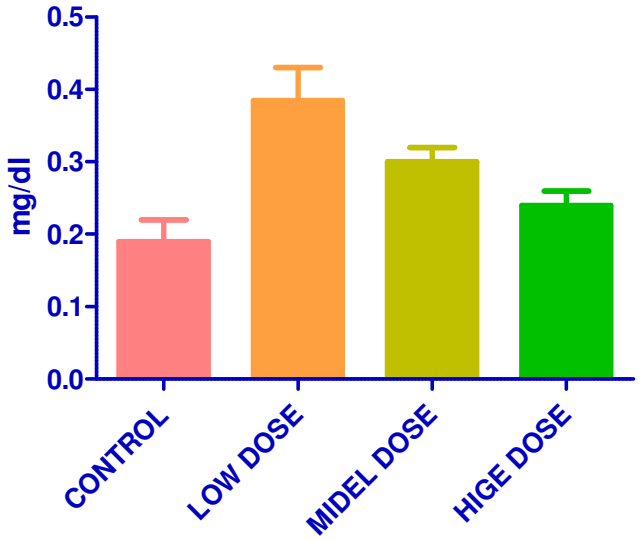
Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.



URIC ACID



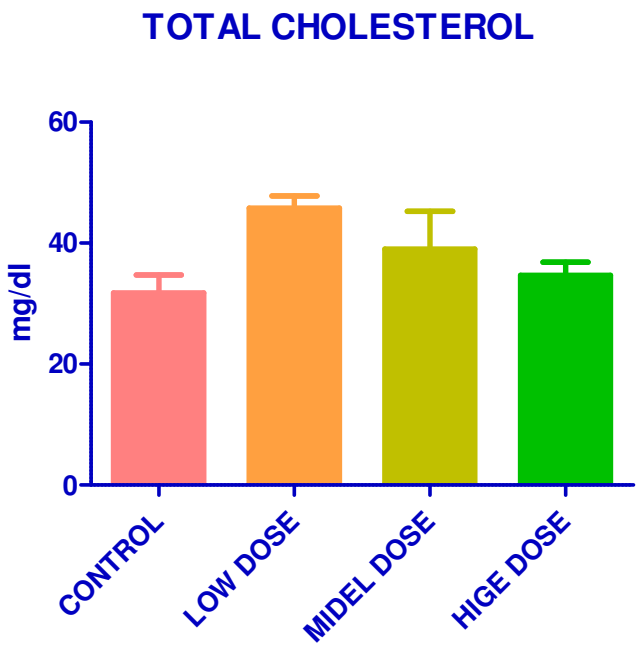
CREATININE

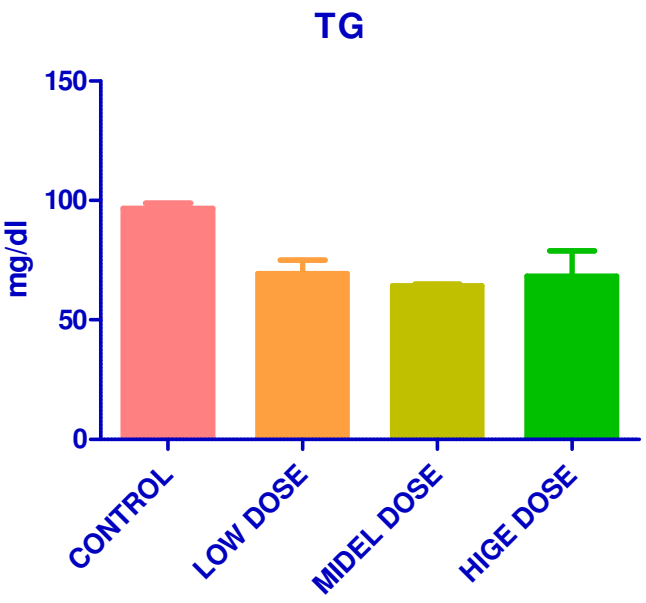


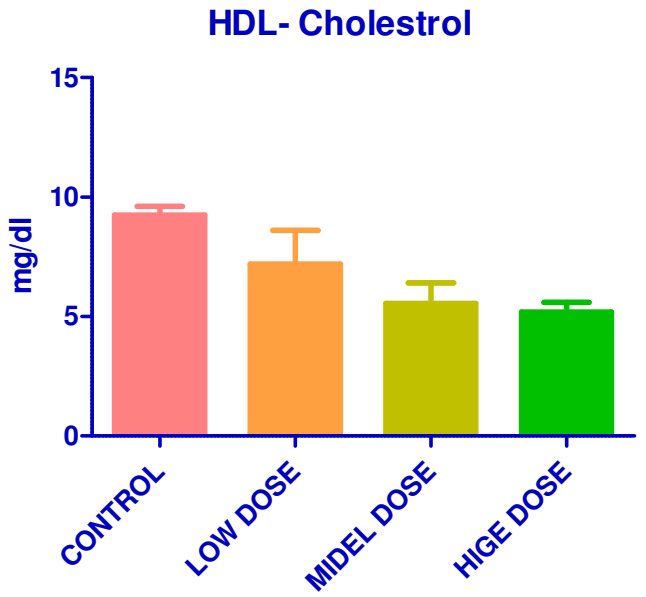
EFFECT OF SUB ACUTE DOSES (28 DAY) 0F MILAGU LEGIYAM WITH HONEY/GHEE ON BIOCHEMICAL PARAMETER (LIPID PROFILE)

Groups	Control	Low Dose	Middle Dose	High Dose
Total cholesterol (mg/dl)	31.8±2.9	45.75±2.05	39±6.2	34.65±2.15
Triglycerides (mg/dl)	96.69±2.09	69.3±5.6	64.35±0.55	68.35±10.55
HDL-Cholesterol (mg/dl)	9.25±0.35	7.2±1.4	5.55±0.85	5.2±0.4

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.




TG
150
100
50
0
mg/dl
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE


HDL- Cholestrol
15
10
5
0
mg/dl
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE

RESULTS:

CLINICAL SIGNS:

All animals in this study were free of toxic clinical signs throughout the dosing period of 28 days.

Mortality:

All animals in control and in all the treated dose groups survived throughout the dosing period of 28 days.

Body weight:

Results of body weight determination of animals Table-1 from control and different dose groups exhibited comparable body weight gain throughout the dosing period of 28 days.

Food consumption:

During dosing and the post-dosing recovery period, the quantity of food consumed by animals from different dose groups was found to be comparable with that by control animals.

Organ Weight:

Group Mean Relative Organ Weights (% of body weight) are recorded in Table No.4 Comparison of organ weights of treated animals with respective control animals on day 29 was found to be comparable similarly.

Hematological investigations:

The results of hematological investigations (Table 4) conducted on day 29 revealed following significant changes in the values of different parameters investigated when compared with those of respective controls; however, the increase or decrease in the values obtained was within normal biological and laboratory limits or the effect was not dose dependent.

Biochemical Investigations:

Results of Biochemical investigations conducted on days 29 and recorded in Table 2 revealed the following significant changes in the values of hepatic serum enzymes studied. When compared with those of respective control. However, the increase or decrease in the values obtained was within normal biological and laboratory limits.

Histopathology:

In histopathological examination, revealed normal architecture in comparison with control and treated animal.

DISCUSSION:

1) All the animals from control and all the treated dose groups up to 500 mg/kg survived throughout the dosing period of 28 days.

2) No signs of toxicity were observed in animals from different dose groups during the dosing period of 28 days.

3) Animals from all the treated dose groups exhibited comparable body weight gain with that of controls throughout the dosing period of 28 days.

4) Food consumption of control and treated animals was found to be comparable throughout the dosing period of 28 days

5) Haematological analysis conducted at the end of the dosing period on day 29, revealed no abnormalities attributable to the treatment.

6) Biochemical analysis conducted at the end of the dosing period on day 29 no abnormalities attributable to the treatment.

7) Organ weight data of animals sacrificed at the end of the dosing period was found to be comparable with that of respective controls.

8) Histopathological examination revealed normal architecture in comparison with control and treated animal.

SUMMARY AND CONCLUSION:

In conclusion **MILAGU LEGIYAM WITH HONEY/GHEE** can be considered safe, as it did not cause either any lethality or adverse changes with general behavior of rats and also there were no observable detrimental effects (100 to 300 mg/kg body weight) over a period of 28 days. Our results have demonstrated that the **MILAGU LEGIYAM WITH HONEY/GHEE** is relatively safe when administered orally in rats.

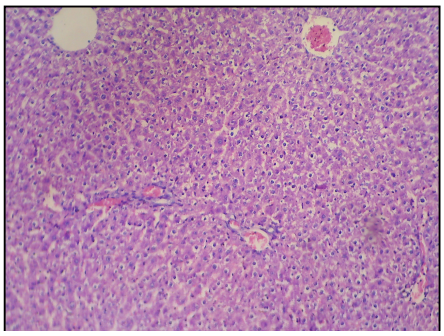
9.0 ABBREVATION

No.	Number
Mg	Milligram
Kg	Kilogram
LD_{50}	Lethal Dose $_{50}$
p.o.	peros
mL	Milliliter
%	percentage

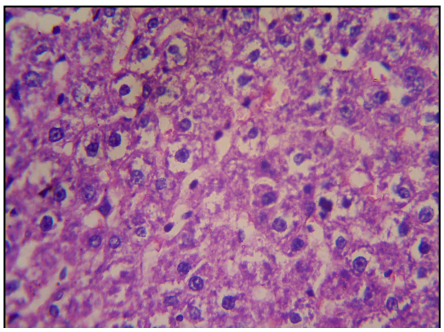
R&D	Research and Development
EDTA	Ethylene Diamine Tetra Acetic Acid
M	Male
g%	Gram percentage
g	Gram
NOAEL	No-Observed-Adverse-Effect-Level
MLD	Minimum Lethal Dose
MTD	Maximum Tolerated Dose
OECD	Organisation of Economic Co-operation and Development
CPCSEA	Committee for the Purpose of Control and Supervision of Experiments on Animals

HISTOPATHOLOGY - TOXICITY STUDY

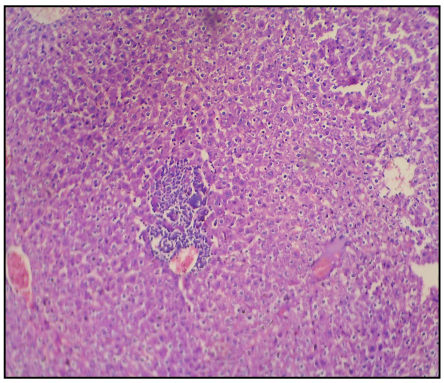
SPECIMEN : A) Liver. Group – : Milagu legiyam



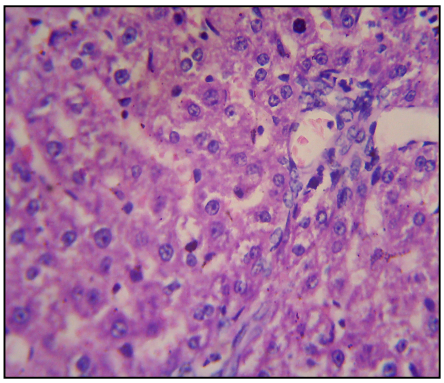
10x shows altered architecture



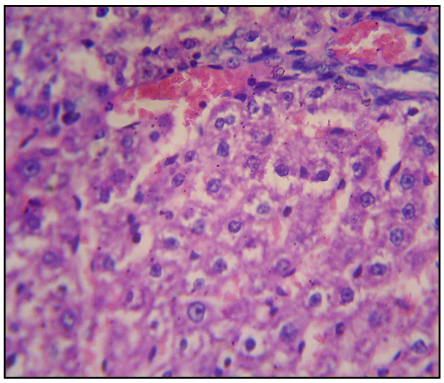
10x shows interface hepatitis with cytoplasmic vacuolation and binucleation



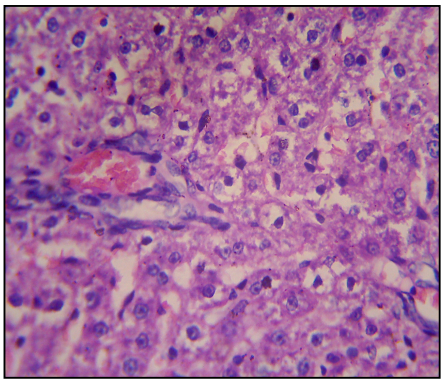
10x shows mild altered architecture with interface hepatitis



40x shows bile duct hyperplasia



40x shows central vein congestion



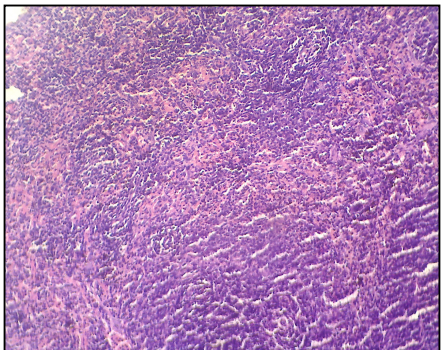
40x shows cytoplasmic vacuolation and bile duct hyperplasia

MICROSCOPIC APPEARANCE:

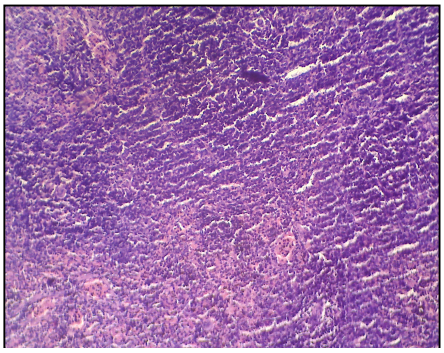
Section from liver shows lobular architecture with interface hepatitis. Individual Hepatocytes shows reactive atypia. Portal triad shows no significant pathology. Central vein and Sinusoids show dilatation.

SPECIMEN : B) spleen.

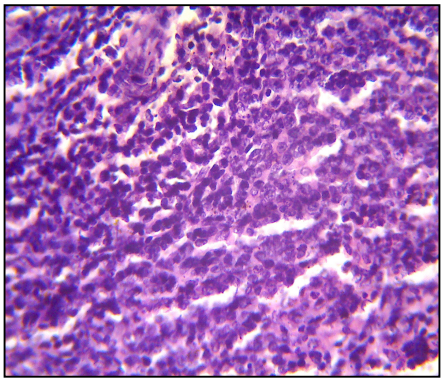
Group – : Milagu legiyam



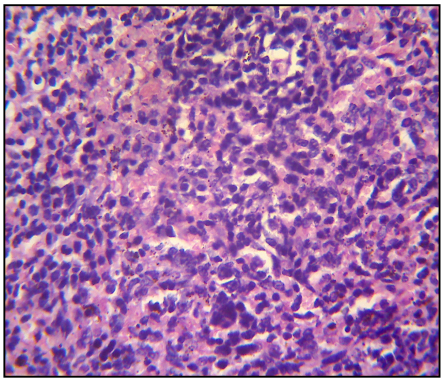
10x shows normal red pulp and white pulp



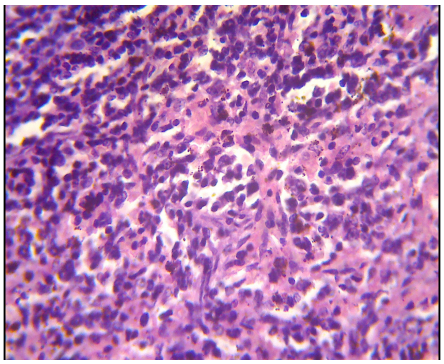
10x shows normaL SPLEEN



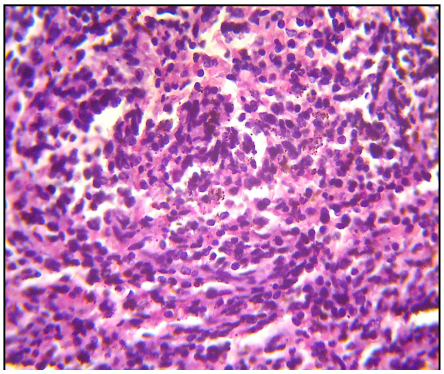
40x shows lymphocytic infiltration



40x shows lymphocytic infiltration



40x shows red pulp with pigment laden macrophages



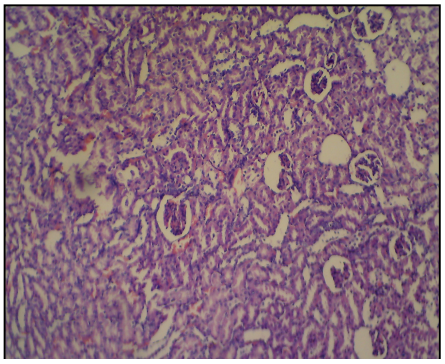
40x shows red pulp

MICROSCOPIC APPEARANCE:

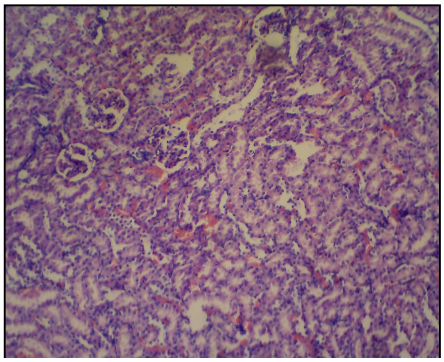
Section studied from spleen shows normal white pulp and red pulp. Red pulp shows pigment laden macrophages and congested vessels. White pulp shows lymphocytic infiltrates forming germinal centre. The pencillar artery shows normal morphology. Megakaryocytes

SPECIMEN : C) Kidney.

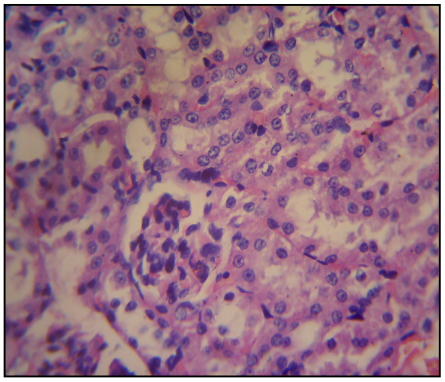
Group – : Milagu legiyam



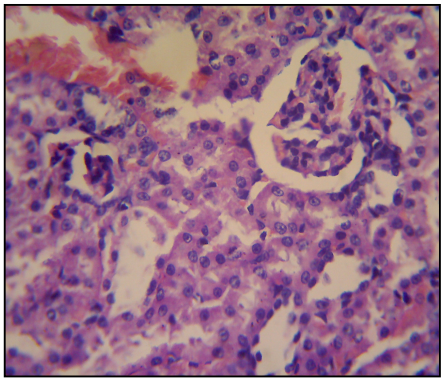
10x shows normal cortex



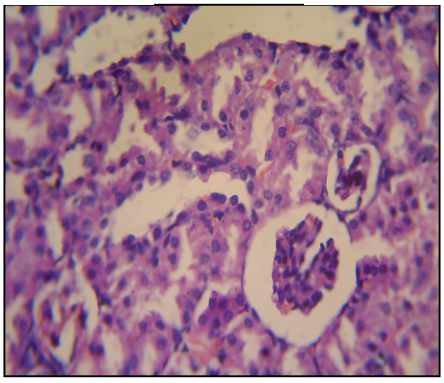
10x shows normal kidney with cortex and medulla



40x shows normal glomeruli (2)



40x shows normal glomeruli with blood vessel congestion



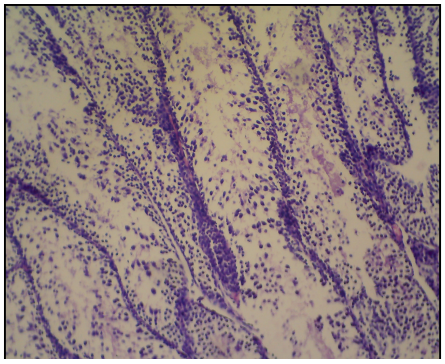
40x shows normal glomeruli

MICROSCOPIC APPEARANCE:

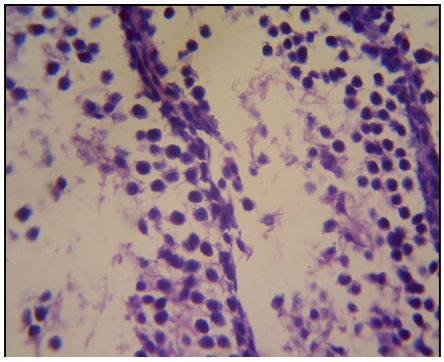
Section from kidney shows both cortex and medulla. Glomeruli and tubules shows no significant pathology. Interstitium shows no significant pathology. Blood vessels show congestion. There is no evidence of toxic changes.

SPECIMEN : D) Testis

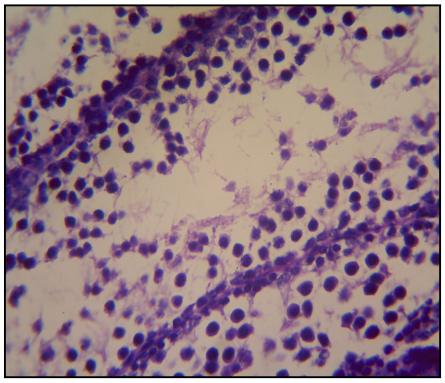
Group – : Milagu legiyam



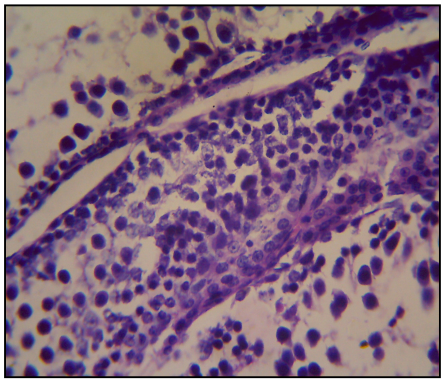
10x shows focal tubules shows maturation arrest



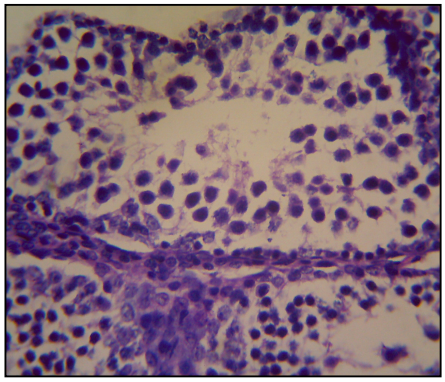
40x shows tubules



40x shows seminiferous tubules shows maturation arrest



40x shows seminiferous tubules



40x shows tubules with sertoli cells (2)

MICROSCOPIC APPEARANCE:

Section from testes with seminiferous tubules showing maturation arrest with lacking of spermatogenesis.

Name : **Ref. No. : [H0 327A/18]**	**Rec.On : 21/03/2018** **Rep.On : 18/04/2018**

HISTOPATHOLOGY

TOXICITY STUDY

SPECIMEN : A) Liver

Group – : D.Subathra – M.L.

GROSS APPEARANCE:

Received a specimen of liver measuring 3.4x2.0x1.4cms.

(PE): Two bits – One block.

MICROSCOPIC APPEARANCE:

Section from liver shows mild altered architecture with interface hepatitis. Individual hepatocytes shows cytoplasmic vacuolation and binucleation. Portal triad shows bile duct hyperplasia. Central vein shows congestion. Sinusoids show dilatation.

Dr.C.R.Ajeethkumar.M.D. (Path).

Consultant pathologists:
Dr.S.Kalyani.M.D. (Path), Dr. C.R.Ajeeth kumar.M.D. (Path),

Checked

Name :	**Rec.On : 21/03/2018**
Ref. No. : [H0 327B/17]	**Rep.On : 18/04/2018**

HISTOPATHOLOGY

Toxicity study

SPECIMEN : B) spleen.

Group – : D.Subathra – M.L.

GROSS APPEARANCE:

Received a specimen of spleen measuring 2.2x0.7x0.5cms.

(PE): Two bits – One block.

MICROSCOPIC APPEARANCE:

Section studied from spleen shows normal white pulp and red pulp. Red pulp shows pigment laden macrophages and congested vessels. White pulp shows lymphocytic infiltrates forming germinal centre. The pencillar artery shows normal morphology. There is no evidence of toxic changes. Megakaryocytes are also seen.

Dr.C.R.Ajeeth kumar. M.D. (Path),

Consultant pathologists:
Dr.S.Kalyani.M.D. (Path), Dr. C.R.Ajeeth kumar.M.D. (Path),

Checked

Name :	**Rec.On : 21/03/2018**
Ref. No. : [Ho 327C/18]	**Rep.On : 18/04/2018**

HISTOPATHOLOGY

Toxicity study

SPECIMEN : Kidney.

Group – : D.Subathra – M.L.

GROSS APPEARANCE :

Received specimen of kidneys each measuring 1.4x0.7x0.4cms and 1.3x0.6x0.4cms.

PE : Two bits – One block.

MICROSCOPIC APPEARANCE:

Section from kidney shows both cortex and medulla. Glomeruli and tubules shows no significant pathology. Interstitium shows no significant pathology. Blood vessels show congestion. There is no evidence of toxic changes.

Dr. C.R.Ajeeth kumar.M.D. (Path).

Consultant pathologists:
Dr.S.Kalyani.M.D. (Path), Dr. C.R.Ajeeth kumar.M.D. (Path),

Checked

Name :	**Rec.On : 21/03/2018**
Ref. No. : [Ho 327D/18]	**Rep.On : 18/04/2018**

HISTOPATHOLOGY

Toxicity study

SPECIMEN : Testis.

Group – : D.Subathra – M.L.

GROSS APPEARANCE :

Received specimen of both testis measuring each 1.0x0.6x0.5cms and 1.0x0.5x0.4cms.

PE : Two bits – One block.

MICROSCOPIC APPEARANCE:

Section from testes with focal seminiferous tubules shows maturation arrest and lacking spermatogenesis. There is no evidence of granuloma/ malignancy seen.

Dr. C.R.Ajeeth kumar.M.D. (Path).

Consultant pathologists:
Dr.S.Kalyani.M.D. (Path), Dr. C.R.Ajeeth kumar.M.D. (Path),